Ministry of Health - MS

National Health Surveillance Agency - ANVISA

RESOLUTION OF THE COLLECTIVE BOARD - RDC No. 81, OF NOVEMBER 5, 2008 (*)

(Published in DOU nº 216, of November 6, 2008)

(Republished in DOU nº 219, of November 11, 2008)

(The provisions applicable to List "C4", substances and antiretroviral medicines were repealed by Resolution – RDC nº 103, of August 31, 2016)

Provides for the Technical Regulation of Imported Goods and Products for Health Surveillance purposes.

The **Collegiate Board of the National Health Surveillance Agency,** using the powers conferred on it by section IV of art. 11 of the Regulation approved by Decree No. 3,029, of April 16, 1999, and in view of the provisions of item II and §§ 1 and 3 of art. 54 of the Internal Regulations approved under the terms of Annex I of Ordinance No. 354 of ANVISA, of August 11, 2006, republished in the DOU of August 21, 2006, in a meeting held on September 11, 2008, and

considering the provisions of Laws No. 6,360, of September 23, 1976, No. 6,368, of October 21, 1976, No. 8,078, of September 11, 1990, No. 8,080, of September 19, 1990, No. 9,434, of 4 of February 1997, No. 9,782, of January 26, 1999, No. 9,787, of February 10, 1999, in Decree-Law No. 986, of October 21, 1969, in Decrees No. 79,094, of January 5, 1977 , nº 87, of April 15, 1991, nº 2,268, of June 30, 1997, and in the Resolutions of the Common Market Group - GMC, internalized in the country;

considering the need to promote the review of control and inspection of goods and products imported under health surveillance, as well as harmonize the terminology used in foreign trade;

considering the need to prescribe obligations of persons, physical or legal entities, under public or private law, involved in these activities,

adopts the following Resolution of the Collegiate Board of Directors and I, President Director, substitute, I determine its publication:

Art. 1 Approve Technical Regulation of Imported Goods and Products for the purposes of Health Surveillance, according to Chapters of this Resolution.

§ 1 Approve model criteria for the purposes of import authorization referred to in this Resolution, to be made available on ANVISA's website, www.anvisa.gov.br.

§ 2 Approve the documentary proof for the purposes of authorization of import referred to in this Resolution, according to the Chapters of this Resolution.

Art. 2 For the purposes of regularizing import services for goods and products referred to in Resolution-RDC no. 61, of March 19, 2004, § 1 of article 1, comes into force with the following wording:

"Art. 1º

.....

§ 1 "Import services carried out through predetermined intermediation are considered to be those provided by a legal entity that promotes customs clearance for the mere import of goods and products subject to health surveillance, acquired abroad, due to a contract signed with a third party, an authorized/licensed company with the National Health Surveillance System - SNVS, which regulates the product before the relevant health surveillance body." (NR)

~~Art. 3º The identification of goods according to the type of administrative procedure and Mercosul Common Nomenclature - NCM contained in Chapter XXXIX of this Resolution, will be made available on the website www.anvisa.gov.br, and will produce legal effects for their classification when importing goods .~~

Art. 3 The Mercosul Common Nomenclature (NCM) of goods subject to administrative treatment by Anvisa will be made available on the Agency's website. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

Single paragraph. The importer must select the administrative procedure appropriate to the type of merchandise when submitting the petition and instructing the import process. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

Art.4 Non-compliance or non-compliance with the provisions of this Resolution constitutes an infraction of a sanitary nature, under the terms of Law No. 6,437, of 1977.

Art. 5 Resolution RDC No. 350, of December 28, 2005, and the Resolution RDC nº 217, of December 15, 2006 and the provisions to the contrary.

Art. 6 This Resolution comes into force on the date of its publication.

MARIA CECÍLIA MARTINS BRITO

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

ATTACHMENT

TECHNICAL REGULATION OF GOODS AND PRODUCTS IMPORTED FOR PURPOSES HEALTH SURVEILLANCE

CHAPTER I

BASIC TERMINOLOGY

1. For the purposes of this Regulation, the definitions in this Chapter will be adopted.

1.1. Sample: representation by quantity, fragments or parts of any raw material, product or other goods covered by this Regulation, strictly necessary to make its nature, species and quality known.

1.2. Fiscal Analysis: that carried out on goods or products covered by this Regulation, on a routine basis, to determine an infraction or verify their compliance with the standards established in the relevant health legislation.

1.3. Control Analysis: one in which a sample of goods or products is taken for importation, prior to their release for consumption in the national territory, and is intended to prove or verify their compliance with the respective identity and quality standard.

1.4. Boarding authorization: authorization to be granted by ANVISA for the import of goods and products, subject to approval prior to the date of their shipment abroad.

1.5. Health Authority: authority directly responsible for applying appropriate health measures in accordance with the relevant legislation and regulations.

1.6. Luggage: objects, new or used, intended for the traveler's personal use or consumption, which, due to their quantity, nature or variety, are compatible with the circumstances of their trip, not allowing the assumption of import for commercial or industrial purposes.

1.6.1. Accompanied Baggage: that which the traveler brings with him, on the same means of transport in which he travels, not subject to a bill of lading or equivalent document.

1.6.2. Unaccompanied Baggage: that which arrives in the country, subject to bill of lading or equivalent document.

1.7. Bioequivalence: demonstration of pharmaceutical equivalence between products presented in the same pharmaceutical form, containing identical qualitative and quantitative composition of active ingredient or active ingredients, and which have comparable bioavailability, when studied under the same experimental design.

1.8. Bioavailability: indicator of the speed and extent of absorption of an active ingredient in a dosage form, based on its concentration/time curve in the systemic circulation or its excretion in the urine.

1.9. Bill of Lading (shipping): document issued, on the date of shipment of the good or product, by the carrier or consolidator, constituting the international transport contract and proof of the disposition of the good or product to the importer (Cargo shipped by air - Air Waybill /AWB , Waterborne cargo -

Landing Bill /BL and Land Loaded Cargo: International Road Transport Bill /CTR).

1.10. Quality Control: measures or set of measures designed to verify conditions of activity, purity, effectiveness and safety of goods and products under health surveillance, by batch or other control representation criteria, as appropriate, in accordance with the relevant legislation.

1.11. Customs clearance of imports: final act of customs clearance.

1.12. Import Customs Clearance: act in a tax procedure that verifies the accuracy of the data declared by the importer in relation to imported goods and products, definitively or not, with a view to their customs clearance, in accordance with the relevant legislation.

1.13. Advance Clearance: type of customs clearance of goods and products in which the registration of the import declaration - DI can be done at the clearance unit, before the arrival of the goods and products.

1.14. Recipient of the shipment: Person to whom the postal item or express.

1.15. Holder of the Product Regularization Document at ANVISA: designation given to the holder of the registration, registration, model authorization, communication, notification or pertinent protocol of the good or product before ANVISA.

1.16. Packaging: wrapper, container or any form of packaging, removable or not, which is intended to cover, package, fill, protect or maintain, specifically or not, imported goods and products.

1.17. External Packaging: that used exclusively for the protection of goods and products in movement (loading, unloading and transport) and storage operations.

1.18. Primary Packaging: packaging that is in direct contact with the good or product and that can consist of a container, wrapper or any other form of protection, removable or not, which is intended for filling or maintaining, covering or packaging.

1.19. Secondary Packaging: wrap intended to contain the primary packaging(s).

1.20. Express Shipping Company, "Courier": one whose predominant activity is the provision of international express transport services, door to door, of express shipments destined for third parties, in a regular and continuous flow.

1.21. International Air Parcel: method of transporting goods and products by airlines, made to order, subject to health control.

1.22. Proficiency testing: material used in programs to determine the performance of specific tests or measurements through inter-laboratory comparisons.

1.23. Split Delivery: import by a single importer that, for reasons of volume or weight of the good or product, cannot be carried out in just one transport vehicle.

1.24. Exporter: person, natural or legal, responsible for shipping goods and products from another country into the national territory.

1.25. Manufacturer: legal entity responsible for the manufacturing unit where the goods and products were processed, and having been produced in more than one country, the additional identification of the legal entities responsible for the manufacturing units where their processing took place.

1.26. Health Inspection: procedures or set of procedures for acts of technical and administrative document analysis, and physical inspection of imported goods or products, with the purpose of eliminating or preventing risks to human health, as well as intervening in health problems arising from the environment , the production and circulation of goods that, directly or indirectly, are related to public health.

1.27. Import: entry into the national territory of goods or products from abroad.

1.28. Importer through predetermined intermediation: legal entity that promotes, in its name, a foreign trade operation involving the import of goods and products under health surveillance acquired by another company that has the regularization of the product in the National Health Surveillance System, or authorized for the import activity raw material used in the pharmaceutical industry.

1.29. Importer: natural or legal person responsible for the entry of goods or products from abroad into the national territory.

1.30. Physical Inspection: set of measures designed to verify compliance with current health legislation.

1.31. Research institution: organization, public or private, legitimately constituted and authorized in which scientific investigations are carried out.

1.32. Import Licensing: electronic application to SISCOMEX (Import Module), by the importer or his legal representative, for non-automatic licensing procedures to verify compliance with requirements for the import of goods and products under health surveillance.

1.33. Place of Entry: port, airport, customs unit or customs border point declared by the competent customs authority for the transit of vehicles and carrying out loading, unloading, storage or passage of goods and products under health surveillance coming from abroad.

1.34. Clearance Location: customs area where the dispatch and customs clearance.

1.35. Free Store: store installed preferably in the primary area of the port or bonded airport where the vessel or aircraft is located, with the purpose of providing airline or maritime companies with products, national or foreign, intended for consumption on board, or selling them to passengers, on international trips, against payment in convertible foreign currency, in accordance with the relevant legislation.

1.36. Batch: quantity of a product obtained in a production cycle of continuous stages and which is characterized by its homogeneity.

1.37. Diplomatic or Consular Bag: volume not subject to size and weight limits, as well as restrictions regarding its opening or retention by the customs authority, sent and transported, respectively, by specific procedures and established instruments, as appropriate, which contains:

a) diplomatic or consular documents, presented by any means physicist;

b) material intended for official use by the representation of the accredited State, notably letterhead, envelopes, stamps, stamps, passport book, decoration insignia;

c) objects and equipment intended for official use by the representation of the accredited State, notably computer and communication equipment, protected by secrecy or whose shipment and customs clearance, under the common import or export regime, may compromise their security.

1.38. Goods or Products Under Health Surveillance: materials, raw materials, inputs, parts and pieces, finished products, bulk products, semi-finished products and fresh products, and others under health surveillance as provided for in Law No. 9,782, of 1999 , comprising, among others, the following classes of goods and products:

a) food: any substance or mixture of substances, in solid, liquid, pasty or any other suitable form, intended to provide the human organism with normal elements, essential for its formation, maintenance and development;

b) cosmetics, personal hygiene products and perfumes: preparations consisting of natural or synthetic substances, for external use on different parts of the human body, such as skin, hair system, nails, lips, external genital organs, teeth and mucous membranes of the oral cavity , with the exclusive or main purpose of cleaning, perfume, changing its appearance and/or correcting body odors, as well as protecting, maintaining or improving its condition;

c) household sanitizer: substance or preparations that have the purpose and utility of sanitizing, disinfesting and disinfecting homes, collective or public environments, places of common use and water treatment, including: insecticide, rodenticide, disinfectant, detergent and their congeners and others ;

d) standard and reference material:

d.1) reference material: material that has one or more property values that are sufficiently homogeneous and well established to be used in calibrating a device, evaluating a measurement method or assigning values to materials and in programs for determining the performance of specific assays or measurements through inter-laboratory comparisons;

d.2) reference standard:

d.2.1) primary - a substance whose high degree of purity and authenticity were demonstrated through analytical tests;

d.2.2) secondary - substance of established quality and purity, compared to a primary standard;

e) in vitro diagnostic products: reagents, standards, calibrators, controls and materials, together with instructions for their use, which contribute to carrying out a qualitative, quantitative or semi-quantitative determination of a human biological sample and which are not intended to fulfill a function anatomical, physical or therapeutic of any kind, which are not ingested, injected or inoculated into human beings and which are used solely to provide information on samples obtained from the human organism;

f) medical product: devices, instruments and accessories used in medicine, dentistry and related activities, as well as in physical education, beautification or aesthetic correction;

f.1) accessory: Product manufactured exclusively for the purpose of integrating a medical product, giving that product a complementary technical function or characteristic;

g) used medical product: medical product that after its use was not subjected to any refurbishment or review process to bring it into the technical and operational conditions foreseen when it was regularized before ANVISA;

h) refurbished medical product: medical product that, after use, has been subjected to a refurbishment or review process, including replacement of components, parts and pieces, and calibration, quality tests, re-sterilization or labeling, among other services necessary for place it in the technical and operational conditions foreseen when it is regularized with ANVISA, under the express responsibility of the company holding its registration;

i) environmental odorizing products: products with an aromatic composition based on natural or synthetic substances, which in appropriate concentrations and vehicles, are mainly intended for odorizing environments;

j) medicine: any pharmaceutical product, technically obtained or prepared for prophylactic, curative, palliative or diagnostic purposes;

l) pieces of clothing: any used pieces of clothing for personal use, including shoes, imported through international donations;

m) hospital clothing: medical products consisting of any clothing item, made of cotton or synthetic fabric, to be used on people and medical-hospital environments;

n) artifacts made of textile and synthetic materials: any pieces of bed and bath linen and other items for use in environments, such as curtains, blankets, sheets, pillowcases, cushions, etc., imported through international donations;

o) raw material: active or inactive substances that are used in the manufacture of medicines and other products under health surveillance, even if they remain unchanged, undergo modifications or are eliminated during the manufacturing process;

p) food raw material: substance of plant or animal origin, in a raw state, which, in order to be used as food, undergoes treatment and/or transformation of a physical, chemical or biological nature;

q) food product: food derived from food raw materials or fresh food with or without addition of other permitted substances obtained through an appropriate technological process;

r) ingredient: any substances, including food additives, used in the manufacture or preparation of a food and which remains in the final product, even if in a modified form;

s) input: drug or ingredient of any nature, intended for the manufacture of products and their containers;

t) cells and tissues: are materials of human nature for therapeutic purposes, including skin, musculoskeletal tissues, heart valve, hematopoietic progenitor cells, germinal cells and tissues and pre-embryos, corneas and other human cells and tissues.

1.39. Movement of Goods and Products under Health Surveillance: boarding, disembarking, transshipment, transportation and storage practices of imported goods or products in yards, buildings and other facilities at waterway terminals, organized ports, airports and customs facilities.

1.40. MERCOSUR Common Nomenclature - Harmonized System - NCM:
nomenclature used to obtain import tax rates and other provisions, within the scope of MERCOSUR.

1.41. Country(s) and place(s) of Manufacture: that place(s) and Country(s) where the good or product was processed and when produced in more than one location and country, the additional identification of the manufacturing units where processing took place.

1.42. Country of Origin: country where the imported good or product is physically located at the time of its acquisition and from where it leaves for Brazil, regardless of the country of manufacture and the final shipping point;

1.43. Gross Weight: total weight of the good or product, including its containers, packaging and other wrappings.

1.44. Net Weight: weight of the good or product free of any packaging or conditioning

1.45. Scientific or Technological Research: that whose results are applied in the health sector and aimed, ultimately, at improving the health of individuals or population groups.

1.45.1. Scientific Research of Health Interest: research whose object does not involve human beings, but its development may pose risk(s) to individual or collective health.

1.46 Research involving human beings: research that, individually or collectively, involves human beings, directly or indirectly, in their entirety or parts of them, including the handling of information or materials.

1.46.1. Clinical Research: any investigation on human beings, involving therapeutic intervention with products registered or subject to registration, aiming to discover or verify the pharmacodynamic, pharmacokinetic, pharmacological, clinical and/or other effects of the product(s) investigated and/or identify adverse events to the product(s) under investigation, investigating their safety and/or effectiveness, which will support their registration or amendment thereof with ANVISA.

1.47. Finished/Finished Product: one that goes through all stages of production and packaging, ready for sale and/or delivery to the consumption.

1.48. Bulk Product: any product that has passed through all production stages, not including the packaging process.

1.49. In Natura Product: food of plant or animal origin, which for immediate consumption requires only the removal of the inedible part and the treatments indicated for its perfect hygiene and conservation.

1.50. Semi-Elaborated Product: mixture of substances that require subsequent production processes in establishments authorized by the health authority, before being sold or delivered for consumption.

1.51. Bonded Precincts:

I - of primary zone, the yards, warehouses, terminals and other places intended for the movement and deposit of goods or products imported or destined for export, which must move or remain under customs control, as well

such as the areas reserved for checking baggage destined for or coming from abroad and the premises of duty-free stores;

II - secondary zone, warehouses, warehouses, terminals or other units intended for the storage of goods and products under the conditions of the previous section, as well as facilities intended for the deposit of international postal shipments subject to customs control.

1.52. Special Customs Regimes:

a) Temporary Admission: that which allows the importation of goods and products, subject to identification and a term of responsibility, for a determined period of stay in the country justified by proof through suitable and appropriate means for this purpose, with total suspension of payment of taxes, or proportional payment to the length of stay, in the case of economic use, subject to prior consent to obtain an import license, in accordance with Decree No. 4,543, of December 26, 2002, Book IV, Chapter III (Customs Regulation) ;

b) Special Deposit - DE: that which allows the storage, with suspension of payment of taxes, of parts, pieces, components and replacement or maintenance materials, for vehicles, machines, equipment, devices and instruments, foreign, nationalized or not, employed in the activities of:

b.1) diagnosis, surgery, therapy and medical research carried out by hospitals, health clinics and laboratories;

b.2) analysis and scientific research, carried out in laboratories.

c) Drawback: incentive to export, applied, in accordance with Decree No. 4,543, of December 26, 2002, in Book IV, Chapter IV, in the form of suspension, exemption and total or partial refund of taxes;

d) Customs Warehouse for Imports: one that allows the storage of foreign goods and products in a bonded area for public use, or stay at a fair, congress, exhibition or similar event held in a private use area, previously bonded for this purpose, for a period of time determined, with suspension of payment of taxes levied on imports;

e) Customs Transit: regime that allows the transport of goods and products, under customs control, from one point to another in the customs territory, that is, from the place of entry of the good or product to the place of clearance.

1.53. International Postal Shipment: goods and products under health surveillance transported through international parcels by the Brazilian Post and Telegraph Company - ECT.

1.54. Express Shipping: document or international order transported by air, by a courier company, which requires speedy transfer and immediate receipt by the recipient.

1.55. Legal Representative: natural or legal person vested with legal powers to carry out acts on behalf of the regulated agent, intended to manage or administer its business within the scope of ANVISA.

1.56. Legally Responsible: natural person designated in statute, articles of association or minutes, responsible for representing, actively and passively, in judicial and extrajudicial acts, the regulated legal entity agent.

1.57. Technical Responsible: natural person legally qualified to carry out professional activities in the various stages of the production process and provision of services in companies, in each establishment.

1.58. Label: printed or lithographed identification, as well as the words painted or engraved with fire, pressure, label or decal, applied directly to containers, packaging, wrappers, wraps, cartridges or any other internal or external packaging protector.

1.59. Integrated Foreign Trade System - SISCOMEX: administrative instrument that integrates the activities of registration, monitoring and control of foreign trade operations, through a single, computerized flow of information.

1.60. Administrative Treatment Table: the one that defines the NCM and the Chapter, Position and NCM highlights relating to goods or products subject to prior and express consent from ANVISA.

1.61. Public Use Bonded Terminals: installation intended for the provision of public services for the movement and storage of goods and products that are under customs control, not located in a port or airport area:

a) Border Customs Station (EAF): located in the primary zone of a border customs point or in a contiguous area;

b) Customs Retroport Terminal (TRA): located in areas adjacent to from an organized port or port facility, bonded;

c) Interior Customs Station (EADI) or Porto Seco: located in areas secondary.

1.62. Health Surveillance: set of actions capable of eliminating, reducing or preventing health risks and intervening in health problems arising from the environment, the production and circulation of goods and the provision of services of health interest, covering:

a) control of consumer goods that, directly or indirectly, relate to with health, including all stages and processes, from production to consumption; It is

b) control of the provision of services that are related, directly or indirectly, to health.

CHAPTER II

GENERAL IMPORT PROVISIONS

The import of goods or products under health surveillance must be preceded by an express favorable statement from the health authority, in accordance with this Regulation.

1. Only the import, delivery for consumption, exposure for sale or to human health in any capacity will be authorized for goods and products under sanitary surveillance, which meet the sanitary requirements set out in this Regulation and relevant sanitary legislation.

1.1. Goods and products under health surveillance, intended for commerce, industry or direct consumption, must have their import authorized as long as they are formally regularized before the National Health Surveillance System with regard to the obligation, where applicable, of registration, notification, registration , model authorization, exemption from registration, or any other form of control regulated by the National Health Surveillance Agency.

1.2. Authorization for the import of goods and products under sanitary surveillance by an individual or legal entity will be mandatory upon compliance with technical-administrative guidelines and an application through a petition, electronic or manual, made available and regulated by ANVISA.

1.2.1. In the event of a request through manual petition, it is mandatory to present the Union Collection Guide (GRU), from the National Treasury Secretariat and its respective proof of payment, as provided for in the legislation, as well as in the importer's power of attorney. , with delegation of powers before ANVISA, to the legal representative responsible for customs clearance.
(Included by Resolution – RDC nº 208, of January 5, 2018)

1.3. The information included in the petition, electronic or manual, referred to in the previous subsection regarding the import of goods and products, in accordance with this Regulation, must faithfully correspond to that found during its inspection and health inspection.

2. On an emergency or temporary basis, considering the international epidemiological context, human, animal or plant, or the implementation of public health programs related to the sanitary control of goods and products and

of individuals or legal entities involved in the manufacturing and service provision processes, the health authority may prohibit the import or entry of the goods or products referred to in subitem 1.38 of Chapter I of these Regulations.

3. The importer and/or holder of product regularization will be responsible for complying with and observing regulatory and legal standards, measures, formalities and requirements for the administrative import process, in all its stages, from shipment abroad to release health in the national territory.

3.1. The provisions of this item will include the obligation to adopt suitable measures, in person and with contracted third parties for the import of goods or products under health surveillance, which avoid or prevent harm to health.

3.2. The provisions of this item will not exempt the contracted third party from complying with and observing the regulatory and legal standards, measures, formalities and requirements set out in this Regulation.

4. When importing goods and products under sanitary surveillance with a tariff classification - NCM/SH - not provided for in Chapter XXXIX of this regulation, the sanitary authority will be exempt from carrying out requirements, boarding authorization and approval or denial operations before SISCOMEX. Import licensing.

4.1. The provisions of this item do not exempt health inspection.

5. The deadlines for the measures, formalities and requirements provided for in this Regulation will begin on the first business day counting from the date of receipt.

6. The import of goods or products under Special Drawback Regime must comply with the provisions of this Regulation.

CHAPTER III

IMPORT MODALITIES

SECTION I

FROM SISCOMEX - IMPORT MODULE

Subsection I

General Provisions

1. The import of goods and products subject to non-automatic licensing in the Integrated Foreign Trade System - SISCOMEX, set out in Chapter XXXIX of this Regulation, intended for individuals or legal entities, under public or private law,

It will be subject to the prior and express consent of ANVISA through approval of the import license, as an entity that is part of the system.

2. The importer of goods and products under sanitary surveillance, in addition to complying with the sanitary requirements set out in this Regulation for the different import purposes, must present to the competent sanitary authority of ANVISA the request for inspection and sanitary release of the import, by means of a petition for inspection and health clearance referred to in subitem 1.2. of Chapter II of these Regulations.

Subsection II

From the Import Licensing Registry

3. Registration of import licensing must be done by the importer or its authorized legal representative, through SISCOMEX, Import Module.

3.1. The importer will be responsible to the competent health authority by the classification of the product in the SISCOMEX Administrative Treatment Table.

3.2. The importer of goods and products subject to non-automatic licensing will be obliged to register, by filling in the fields of the "Supplier Form" of the Import License-LI, in SISCOMEX, the information related to the manufacturer and exporter.

3.3. The importer of devices, instruments and accessories belonging to the medical product class will be obliged to register in the fields of the "commodity form", of the Import License-LI, in SISCOMEX, information relating to:

a) identification of the product, name, specification (each specification must correspond to an item) and model or commercial presentation, as well as the parts and accessories that accompany it;

b) condition of the product, whether new or refurbished.

~~3.4. The importer must register in the "complementary information" field of the Import License-LI:~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~a) regularization number or code of the importing company in relation to Company Operating Authorization specifying activity(ies) when it comes to the import of products belonging to the classes of medicines, cosmetics, perfumes, personal hygiene products, sanitizing products, medical products, in vitro diagnostic products, raw materials and inputs intended for pharmaceutical industry; as well as outsourced imports under account and order status;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~b) number or code of the regularization of the food importing company regarding the Operating License/Alvará with the competent health body;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~3.5. In the "merchandise form" field of the Import License - LI, the regularization of the product and its validity in the National Health Surveillance System - SNVS.~~

3.5. When importing products under health surveillance that can be regularized by Anvisa, the importer must register in the appropriate field of the petition for health inspection and release, electronic or manual, the regularization number of the product, as well as the batch number, or starting or series or part number. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

4. The import of products intended for industry and commerce must be carried out exclusively through registration in SISCOMEX, Import Module, respecting the guidelines for other import purposes provided for in the other Chapters of this Regulation.

~~5. The import of goods and products when subject to non-automatic licensing - LI - SISCOMEX, set out in the MERCOSUR Common Nomenclature - NCM, must comply with the administrative procedures and documentary requirements included in Chapter XXXIX of this Regulation.~~

5. The import of goods and products, when subject to non-automatic licensing - LI - SISCOMEX, set out in the MERCOSUR Common Nomenclature (NCM), must comply with the administrative procedures and documentary requirements included in this Regulation. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

Subsection III

Import Licensing Shipping Authorization

6. No shipment authorization or approval of Import Licensing-LI will be granted for goods and products included in the administrative procedures described in Chapter XXXIX, which do not meet the sanitary requirements set out in this Regulation or in other sanitary legal diplomas in force.

7. ANVISA's technical sanitary analysis for the purposes of authorizing shipment abroad in licensing the import of goods or products under sanitary surveillance will lose its effects, for the purposes of this Regulation, 120 (one hundred and twenty) days after its approval by the sanitary authority .

7.1. The provisions of this item will exclude technical analysis for the purposes of authorizing shipment abroad in licensing the import of goods or products under health surveillance, linked to public health programs or scientific, technological and innovation research (in the form of Law) which will lose its effects, for the purposes of this Regulation, 360 (three hundred and sixty) days from its filing with ANVISA.

Subsection IV

Granting Import Licensing

~~8. The granting of Import Licensing by ANVISA will imply the inspection of goods and products before customs clearance, at the discretion of the competent health authority or whenever required by virtue of this Regulation.~~ **(Revoked by Resolution – RDC nº 228, of May 23, 2018)**

9. Import Licensing will be granted after the importer has complied with the sanitary requirements or in the cases provided for in the Chapters of this Regulation.

Subsection V

Substitute Import Licensing

10. The approval of the Replacement Import Licensing by the health authority will occur from a fiscal context, if conclusive and satisfactory, linked to the import licensing that preceded it, provided that the change that provided this substitute registration - SISCOMEX - Import Module, has been informed and does not appear to be in disagreement with the inspection and/or conclusion of the previous health inspection.

10.1. In cases of replacement of the LI, resulting from specific changes in information of a monetary, exchange rate and tax nature, without implications for health inspection and whose shipment has already been authorized in the replaced LI, the replacement LI is exempt from a new statement from the technical sector competent.

Subsection VI

Validity of the Import Process

11. The import/DATAVISA process that contains the Petition referred to in Chapter II, subitem 1.2, after the period of up to 150 (one hundred and fifty) days counting from its filing with ANVISA, must be rejected and filed with the System of DATAVISA Information.

12. The import process, referred to in subitem 7.1, which contains the Petition referred to in Chapter II, subitem 1.2., after the established deadline must be rejected and filed with the DATAVISA Information System.

SECTION II

EXPRESS SHIPPING, POSTAL SHIPPING AND INTERNATIONAL AIR PARCEL

13. The import of goods or products by means of express shipment, postal shipment or international air parcel, intended for individuals or legal entities, of public or private law, will be subject to the sanitary requirements set out in this Regulation, other sanitary standards , or determined by the health authority.

13.1. Sanitary inspection will be required before the customs clearance and delivery for exhibition or human consumption purposes.

13.2. It is authorized, in the development of health surveillance in customs areas installed in companies that operate postal or express shipments, the use of technical resources made available by scanner equipment, with a view to viewing and perceiving products under health surveillance.

13.2.1. The visualization referred to in the previous sub-item should serve as guidance for the implementation of more precise tax behaviors, in the impossibility of daily tax coverage for 100% of the goods or products under its jurisdiction.

14. The following will be prohibited from entering the national territory:

a) prohibited goods and products provided for in Procedure 1A of this Regulation and in other normative acts issued by the Boards that make up the Collegiate Board of ANVISA.

b) goods and products lacking identification in their original primary and/or secondary packaging.

15. The competent sanitary authority, in office at the place of clearance, is authorized to grant immediate sanitary rejection of the good, material or product under import, which has not had its nationalization authorized, due to non-compliance with the sanitary requirements in force in the national territory.

15.1. Goods, materials or products whose handling operations for rejection purposes put the health of people under international transport or occupationally exposed at risk will be excluded from the provisions.

16. The goods or products under health surveillance referred to in this Chapter cannot be characterized, in quantity imported or frequency of import, for the purposes of trade or resale.

Subsection I

Express Shipping

17. The express shipping company responsible for importing the good or product under health surveillance must present to the competent ANVISA health authority the request, by means of a petition, for inspection and health release referred to in subitem 1.2. of Chapter II of these Regulations, accompanied by the following documents:

a) bill of lading linked to import - MAWB and HAWB.

b) Union Collection Guide, from the National Treasury Secretariat - GRU, as provided for in relevant health legislation.

17.1. The document referred to in the previous item, item "a", must be presented in its original carbon or electronic form, which will be retained.

17.2. The following information will be considered mandatory for the purposes of technical analysis of the import by the health authority and mandatory presentation, in the case of imports carried out by a legal entity:

a) commercial name, when it is a finished product or in bulk, when applicable;

b) name of the active ingredient that is the basis of the medication formulation;

c) the common name or technical, chemical or biological name of the good or product, when it is an input or raw material intended for the production of medicines, cosmetics, perfumes, personal hygiene products, sanitizing products and in vitro diagnostic products ;

d) the name of the food raw material;

e) purpose of import, according to Table I of Chapter XL, of this Regulation, in cases of import by legal entity;

f) product class, in accordance with item 1.38 of Chapter I of these Regulations;

g) nature of the product, according to Table II of Chapter XL, of this Regulation, in cases of import by legal entity;

h) condition of the medical product (new or refurbished);

i) name of the transport company and when applicable the CNPJ;

j) name, CNPJ or CPF and full address of the product importer;

l) name and full address of the sender of the product.

17.3 Additional information will be considered, at the discretion of the health authority, for the purposes of conclusive technical analysis of the import, in the case of imports carried out by an individual for their own or individual use in quantities and frequencies that do not constitute commerce:

a) commercial name when it is a finished product when applicable;

b) name of the active ingredient that is the basis of the medication formulation;

c) purpose of import, according to Table I of Chapter XL, of this Regulation;

d) product class, in accordance with subitem 1.38 of Chapter I of these Regulations;

e) nature of the product, according to Table II of Chapter XL, of this Regulation;

f) condition of the medical product (new or refurbished);

g) name, CNPJ or CPF and full address of the recipient of the product;

h) name and full address of the product sender.

Subsection II

Postal Shipping

18. The external packaging of the postal shipment must contain information relating to the general identification of the imported good(s) or product(s) under health surveillance and the name and address of the recipient.

19. Additional information will be considered, at the discretion of the health authority, for the purposes of conclusive technical analysis of the import:

a) commercial name when it is a finished product when applicable;

b) name of the active ingredient that is the basis of the medication formulation;

c) purpose of import, according to Table I of Chapter XL, of this Regulation;

d) product class, in accordance with subitem 1.38 of Chapter I of these Regulations;

e) nature of the product, according to Table II of Chapter XL, of this Regulation;

f) condition of the medical product (new or refurbished);

g) name, CNPJ or CPF and full address of the recipient of the product;

h) name and full address of the product sender.

Subsection III

International Air Parcel

20. The company that operates a regular air transport service responsible for importing international air orders of medicines and foods for continuous use or special nutrition, intended for individuals residing in the country, must present the good or product to the competent health authority of ANVISA , accompanied by the following documents:

a) declaration for the purposes of relevant customs clearance;

b) prescription in accordance with item 4, Section II, Chapter XII;

c) invoice or purchase note;

d) authorization from the recipient for customs clearance purposes.

SECTION III

SIMPLIFIED NON-ELECTRONIC IMPORT DECLARATION

21. The import of goods or products intended for individuals or legal entities, under public or private law, whose customs clearance is carried out by means of a Simplified Import Declaration - DSI, non-electronic, will be subject to the sanitary requirements set out in this Regulations and others determined by the health authority.

21.1. Sanitary inspection will be required before the customs clearance and delivery for exhibition or human consumption purposes.

22. In addition to complying with the sanitary requirements set out in this Regulation for the different import purposes, the importer must present to the competent ANVISA sanitary authority the request for inspection and sanitary release of the import, by means of a petition for inspection and release

health referred to in subitem 1.2. of Chapter II of these Regulations, accompanied, where appropriate, by the following documents:

a) bill of lading linked to import - MAWB and HAWB, wherever applicable;

b) Union Collection Guide, from the National Treasury Secretariat - GRU, as provided for in relevant health legislation.

22.1. The document referred to in the previous item, item "a", must be presented in its original carbon or electronic form, which will be retained.

22.2. Mandatory information will be considered for technical analysis purposes import by the health authority and mandatory presentation:

a) commercial name, when it is a finished product or in bulk, when applicable;

b) name of the active ingredient that is the basis of the medication formulation;

c) the common name or technical, chemical or biological name of the product, when it is an input or raw material intended for the production of medicines, cosmetics, personal hygiene products, sanitizing products and in vitro diagnostic products;

d) the name of the food raw material;

e) purpose of import, according to Table I of Chapter XL, of this Regulation;

f) product class, in accordance with subitem 1.38 of Chapter I of these Regulations;

g) nature of the product, according to Table II of Chapter XL, of this Regulation;

h) name of the transport company and, where applicable, CNPJ;

i) name, CNPJ or CPF and full address of the product importer;

j) name and full address of the sender of the product.

~~**SECTION IV**~~

~~**ACCOMPANIED AND UNACCOMPANIED BAGGAGE**~~

(Revoked by Resolution - RDC nº 28, of June 28, 2011)

~~23. Finished products belonging to the classes of medicines, foods, medical products, in vitro diagnostic products, cosmetics, personal hygiene and sanitizing products coming from abroad and transported or intended for individuals, through accompanied or unaccompanied baggage, subject to The health requirements set out in this Regulation and others determined by the health authority, at the place of clearance in the national territory, must be complied with.~~ **~~(Revoked by Resolution - RDC nº 28, of June 28, 2011)~~**

~~24. In the development of health surveillance, the use of technical resources made available by scanner equipment is authorized, with a view to visualizing and perceiving goods and products under health surveillance.~~ **~~(Revoked by Resolution - RDC nº 28, of June 28, 2011)~~**

~~24.1. The visualization referred to in the previous item should serve as a guide for more precise tax behavior, especially when it is impossible to have daily tax coverage for 100% of the products under its tax jurisdiction.~~ **~~(Revoked by Resolution - RDC nº 28, of June 28, 2011)~~**

~~25. The entry into the national territory of baggage accompanied or unaccompanied by goods and products coming from abroad and transported by an individual, not characterized as for personal or individual consumption, will be prohibited.~~ **~~(Revoked by Resolution - RDC nº 28, of June 28, 2011)~~**

~~25.1. The entry of goods and products belonging to the classes of medicines and foods for continuous use or special nutrition, as well as products for in vitro diagnosis and medical products, intended for personal consumption will only be authorized upon presentation to the health authority of the professional's prescription pertinent, as set out in Chapter XII, Section II.~~ **~~(Revoked by Resolution - RDC nº 28, of June 28, 2011)~~**

~~25.2. Exceptions to the provisions are the cases provided for in the importation referred to in the Chapter XXXIV.~~ **~~(R~~evoked by Resolution - RDC nº 28, of June 28, 2011)**

~~26. Entry into the national territory will be prohibited for:~~ **~~(Repeale~~d by Resolution - RDC nº 28, of June 28, 2011)**

~~a) cells and tissues intended for therapeutic purposes not authorized by the competent technical area of ANVISA headquarters;~~ **~~(Revoked by Reso~~lution - RDC nº 28, of June 28, 2011)**

~~b) prohibited goods and products provided for in Procedure 1-A of this Regulation and in other normative acts issued by the Boards that make up the Collegiate Board of ANVISA.~~ **~~(Revoked by Resolution - RDC nº 28, of June 28, 2011)~~**

~~c) goods and products lacking identification in their original primary and/or secondary packaging.~~ **~~(Revoked by Resolution - RDC nº 28, of June 28, 2011)~~**

~~27. In cases of interdiction and/or seizure, at the discretion of the health authority in charge of the customs clearance terminal for baggage, the entry into national territory of part of that good or product may be authorized for the exclusive purpose of maintaining clinical treatment. imported.~~ **~~(Revoked by Resolution - RDC nº 28, of June 28, 2011)~~**

CHAPTER IV

COMPANIES

1. Only the goods and products referred to in this document may be imported Regulation of companies authorized by ANVISA for this activity.

1.1. Companies importing food, food raw materials or food products will be excluded from the provisions of this item, which must present, upon arrival of the good or product, an official company regularization document issued by the state or municipal authority.

1.1.1 In the case of outsourcing the storage activity, it will be mandatory to present to the health authority at the place of clearance, the contract and regularization of the company that will promote the storage, in accordance with good storage practices provided for in the relevant health legislation.

1.2. A company that carries out the activity of importing raw materials that will integrate manufacturing processes of products belonging to the classes of cosmetics, perfumes, personal hygiene products, medical products and products for diagnostics is exempt from regularization with ANVISA regarding the Operating Authorization. vitro and sanitizers.

Note: See art. 5th, IV of Resolution – RDC nº 16, of April 1, 2014.

2. The import of:

2.1. raw materials and pharmaceutical inputs intended for the manufacture of medicines by a company that does not hold an Operating Authorization or Special Operating Authorization, as applicable;

CHAPTER V

GOODS AND PRODUCTS

1. Goods and products under health surveillance must present themselves, upon arrival in the national territory:

a) in compliance with the Identity and Quality Standards - PIQ, required by the relevant health legislation;

b) with an expiration date and in force, in accordance with relevant legislation;

c) with primary and secondary packaging identified in accordance with Good Manufacturing Practices – GMP

d) with external packaging identified for transport, movement and storage.

2. Mandatory identification of the external packaging of each volume of imported products covered by this item will consist of:

a) commercial name, when it is a finished product or in bulk, when applicable;

b) name of the active ingredient based on the formulation, in the case of exclusive import of medicine;

c) common name or technical, chemical or biological name of the product, when it is an input or raw material intended for the production of medicines, cosmetics, perfumes, personal hygiene products, sanitizing products and products for in vitro diagnosis and medical products;

d) name of the food raw material;

e) number or code of the batch or production batch of the packaged products;

f) name of the manufacturer, city and country;

g) special precautions for storage, including those related to maintaining the identity and quality of the good or product, such as temperature, humidity, light, among others.

2.1. They will be excluded from meeting the requirements included in subitem anterior:

a) the product whose mandatory identification on the external packaging is regulated, in accordance with this Regulation, and in specific health legislation;

b) the product referred to in Procedures 1 and 1-A, of Chapter XXXIX, of these Regulations.

3. Used clothing items and artifacts made of textile and synthetic materials, whether used or not, the subject of international donations intended for legal entities, under public or private law, when imported, must be protected and identified by external packaging.

3.1. Mandatory identification of the external packaging of the goods or products covered by this item will consist of:

a) specification of clothing items for personal use;

b) identification of the country of origin,

c) country and city of origin;

d) identification of the recipient;

e) identification of the condition of the good or product, whether new, used or reconditioned.

4. The import of finished, semi-finished or bulk products or raw materials will be prohibited, for industrial, commercial purposes, distribution at fairs or events, market research and international donation, with an expiry date expiring in next 30 (thirty) days from its health release.

4.1. Excluded from the provisions of this item are imported finished, semi-finished or bulk products for industrial purposes or finished products imported for commercial purposes, the period of which defined when approved by ANVISA or its manufacturer is shorter to 180 (one hundred and eighty) days.

5. The import of pharmaceutical inputs intended for the manufacture of medicines that have not yet had their therapeutic efficacy evaluated by ANVISA is prohibited.

5.1. This item excludes the import of samples for the strict purpose research, development of formulations and medical and scientific work.

~~**CHAPTER VI**~~

~~**REGISTRATION - CUSTOMS BROKER**~~

(Revoked by Resolution – RDC nº 74, of May 2, 2016)

~~1. The registration of the customs broker will be mandatory with the Coordination of Health Surveillance of Ports, Airports and Borders of the State where customs clearance will take place, which, once the conditions of the relevant legislation are met, will carry out the competent certification.~~ ~~**(Revoked by Resolution – RDC nº 74, of May 2, 2016)**~~

~~2. Registration will take place upon presentation of the following documents and information:~~ ~~**(Revoked by Resolution – RDC nº 74, of May 2, 2016)**~~

~~a) copy of the legal entity's registration in the National Register of Legal Entities – CNPJ;~~ ~~**(Revoked by Resolution – RDC nº 74, of May 2, 2016)**~~

~~b) copy of the articles of incorporation or minutes of incorporation, registered with the Board Commercial, and its changes, when applicable, with mandatory and explicit information on the objectives of the required activity;~~ **(Revoked by Resolution – RDC nº 74, of May 2, 2016)**

~~c) importer's power of attorney, which must be presented in its original form and copy, for authentication, or previously authenticated, which will be retained, and cannot be valid for more than 12 (twelve) months from its signature. Said instrument must contain, in the delegation of powers to the National Health Surveillance Agency - ANVISA, the following sub-paragraphs:~~ **(Revoked by Resolution – RDC nº 74, of May 2, 2016)**

~~c.1) "petition for inspection and sanitary release for import of products under sanitary surveillance";~~ **(Revoked by Resolution – RDC nº 74, of May 2, 2016)**

~~c.2) "monitoring the stages of health inspection of goods or products under health surveillance";~~ **(Revoked by Resolution – RDC nº 74, of May 2, 2016)**

~~c.3) "receipt of counter-test samples of products under health surveillance for fiscal or control analysis";~~ **(Revoked by Resolution – RDC nº 74, of May 2, 2016)**

~~c.4) "become aware of legal terms and other documents related to the inspection of products under health surveillance, and presentation of means of defense, such as objections, production of evidence and filing of appeals";~~ **(Revoked by Resolution – RDC nº 74, of May 2, 2016)**

~~And additionally, the sub-paragraphs:~~ **(Repealed by Resolution – RDC nº 74, of May 2, 2016)**

~~c.5) "subscription of a Term of Custody and Responsibility to authorize the departure of products under health surveillance from the customs area with reservations";~~
(Revoked by Resolution – RDC nº 74, of May 2, 2016)

~~c.6) "enforcement of the destruction of products under health surveillance in the form of health legislation".~~ **(Repealed by Resolution – RDC nº 74, of May 2, 2016)**

~~d) document signed by the importer's legal representative with a nominal list of the employees legally qualified to execute the powers delegated in the power of attorney referred to in the previous paragraph, with a copy of the respective Individual Taxpayer Registration documents - CPF.~~ **(Revoked by Resolution – RDC nº 74, of May 2, 2016)**

CHAPTER VII

THIRD PARTY IMPORTATION

1. For the purposes of this Chapter, outsourced imports will be considered:

1.1. between companies regularized with ANVISA regarding the authorization of operation for importing or importing and manufacturing activities;

1.2. import carried out through predetermined intermediation;

1.3. by public public health bodies and institutions and multilateral international organizations.

2. The provisions of this Chapter will apply to the import of products in the form of finished products or in the intermediate stage, semi-finished stage and in bulk, of their production or manufacturing process.

2.1. Goods or products subject to specific legislation are excluded from the provisions of the previous item.

3. The import of products at an intermediate stage of their production or manufacturing process will only be permitted if the company holding the product regularization document with ANVISA is authorized for import and manufacturing activities.

4. Entry into the national territory must be done through registration in the Integrated Foreign Trade System - SISCOMEX.

5. The holder of the product regularization before ANVISA will be responsible for:

a) the obligation to comply with and observe regulatory and legal standards, measures, formalities and requirements for the administrative import process referred to in this Chapter, in all its stages, from shipment abroad to sanitary release in the national territory.

b) the execution of laboratory tests to verify the guarantee and maintenance of the identity and quality of the imported product, finished or in an intermediate stage of its production or manufacturing process, semi-finished and bulk product stages, in a suitable laboratory environment installed in the national territory, part of the Operating Authorization or Operation Authorization register.
Special Operation authorized by ANVISA;

c) compliance with Good Practices in operations linked to transport, movement and storage of the products covered by this Chapter;

d) responsibility for the required information, even if provided by thirdly, regarding imported goods or products.

5.1. The provisions of this item will include the obligation to adopt appropriate measures, in person and with third parties contracted for the import of the products referred to in this Chapter, that avoid or prevent harm to health.

5.2. The provisions of this item will not exempt the outsourced company from complying with and observing the regulatory and legal standards, measures, formalities and requirements set out in this Regulation.

6. For the purposes of collecting the Health Surveillance Inspection Fee, the size of the legal entity holding the product regularization before ANVISA will be considered.

~~7. Outsourced imports will take place with the consent of the health authority upon presentation of the following documentation at the place of clearance for each import:~~

~~a) Petition for Inspection and Health Release referred to in subitem 1.2 of Chapter II of these Regulations;~~

~~b) declaration from the legal entity holding the regularization of the product with the ANVISA authorizing the import, in its original form and copy, for authentication, or previously authenticated, which will be retained, which must:~~

~~i) be linked to a single and exclusive legal entity, and the transfer of this authorization is prohibited;~~

~~ii) have legal validity, including not being valid for more than 90 (ninety) days from its signature;~~

~~iii) be signed by its legal guardian or legal representative, and by its technical responsible, with notarized signature;~~

~~iv) express the commitment to observe and comply with the standards and procedures established by health legislation, as well as being aware of the penalties to which it will be subject, under the terms of Law No. 6,437, of August 20, 1977.~~

~~c) instrument of representation of the legal entity holding the regularization of the product with ANVISA in favor of the legal guardian or legal representative, in its original form and copy, for authentication, or previously authenticated, which will be retained.~~

~~d) Import Authorization through predetermined intermediation, as per Chapter VIII;~~

7. Outsourced imports will take place with the consent of the health authority, upon presentation, for each import, of the following documentation:
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

a) Petition for Inspection and Health Release referred to in subitem 1.2 of Chapter II of this Resolution;
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

b) declaration from the legal entity holding the regularization of the product with the ANVISA, authorizing the import, and must: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

i) be linked to 1 (one) single and exclusive legal entity, and the transfer of this authorization is prohibited; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

ii) have legal validity and cannot be valid for more than 90 (ninety) days from its signature; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

iii) be signed by its legal guardian or legal representative, and by its technical manager; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

iv) express commitment to observance and compliance with the standards and procedures established by health legislation, as well as awareness of the penalties to which it will be subject, under the terms of Law no. 6,437, of August 20, 1977. **(Wording given by Resolution – RDC no. 208, of January 5, 2018)**

c) Import Authorization through predetermined intermediation, as per Chapter VIII. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

8. Imports promoted by public bodies and institutions that do not have the regularization of goods or products before ANVISA are exempt from presenting the documentation contained in paragraphs "c" and "d" of item 7.

9. In the event of importing finished products belonging to the food class, the legal entity must comply with the provisions of Chapter IV of this Regulation, regarding the criteria relating to companies authorized for this activity.

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER VIII

IMPORT AUTHORIZATION PROCEDURE BY INTERMEDIATION DEFAULT

IMPORT AUTHORIZATION BY PREDETERMINED INTERMEDIATION

1. DATA OF THE CONTRACTOR HOLDING THE PRODUCT REGULARIZATION:

1.1 - CNPJ No.:

1.2 - CORPORATE NAME:

1.3 - FULL ADDRESS:

Neighborhood		POCKET	
County		UF:	
DDD:	Telephone:	DDD:	Fax:
Electronic address (e-mail):			
1.4. Name of Legal Representative:			
1.4.1. CPF:			
1.5. Name of Technical Responsible:			
1.5.1. CPF:			
1.5.2. Class Council Code:			
1.5.3. No. from the Class Council:			

1.6 - HEALTH OPERATING LICENSE:

1.6.1 - N°:
1.6.2 - Expiry Date:
1.6.3 - Municipality:

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

1.7- AFE Nº:

1.8 - AE Nº:

2. LIST OF GOODS OR PRODUCTS UNDER IMPORTATION PROCEDURE BY PREDETERMINED INTERMEDIATION:

Item: 1	ANVISA regularization Manufacturer name Country of manufacture		
Commercial name			
Presentation:			
Item: 2			
Presentation:			

3 - CONTRACTOR DATA:

3.1 - CNPJ No.:

3.2 - CORPORATE NAME:

3.3 - AFE Nº :

3.4 - FULL ADDRESS:

Neighborhood		POCKET	
County		UF:	
DDD:	Telephone:	DDD:	Fax:
Electronic address (e-mail):			
3.5. Name of Legal Representative:			
3.5.1. CPF:			

REPRESENTATIVE OR RESPONSIBLE

~~**CHAPTER IX**~~

~~**IMPORTATION BY HOSPITAL UNIT OR HEALTH CARE ESTABLISHMENT HEALTH**~~ **(Revoked by Resolution – RDC nº 383, of May 12, 2020)**

~~1. The direct import by a hospital unit or health care establishment that provides therapeutic and diagnostic services, of products belonging to the classes of medicines, medical products and in vitro diagnostic products must be preceded, upon shipment abroad, by Import Licensing registration with SISCOMEX, according to Chapter III, Subsection II.~~

~~1. The direct import by a hospital unit or healthcare establishment that provides therapeutic and diagnostic services, of products belonging to the classes of medicines, medical products and in vitro diagnostic products must be preceded by Import Licensing registration with SISCOMEX, as per Chapter III, Section I, Subsection II.~~ ~~**(Wording given by Resolution – RDC nº 208, of January 5, 2018) (Revoked by Resolution – RDC nº 383, of May 12, 2020)**~~

~~1.1. The Import Licensing referred to in this Chapter must be submitted to the health authority, in office at the place of clearance of the product, by submitting an application, through the Petition for Inspection and Sanitary Release of Import, referred to in subitem 1.2. , Chapter II of this Regulation, the following requirements are met:~~

~~a) The product must be regularized with ANVISA upon arrival in the national territory;~~

~~b) presentation by the importer of the document of its licensing by the health surveillance body, or Health Permit, with the State, Federal District or County;~~

~~c) The company must be regularized with ANVISA, regarding Authorization Special Operation for the activity of importing medicines subject to special control, under the terms of Ordinance SVS/MS nº 344, of 1998;~~

~~d) declaration from the legal entity holding the regularization of the product, with ANVISA authorizing the import, which will be presented in its original form and copy, for authentication, or previously authenticated~~, ~~which will be retained, and must also:~~

~~i) be linked to a single and exclusive legal entity, and the transfer of this authorization is prohibited;~~

~~ii) have legal validity, including not being valid for more than 90 (ninety) days from its signature;~~

~~iii) be signed by its legal guardian or legal representative, and by its technical responsible, with notarized signature;~~

~~iv) express the commitment to observe and comply with the standards and procedures established by health legislation, as well as being aware of the penalties to which it will be subject, under the terms of Law No. 6,437, of August 20, 1977.~~

~~1.1 The Import Licensing referred to in this Chapter must be submitted to the health authority, through the Petition for Import Inspection and Sanitary Release referred to in subitem 1.2. of Chapter II of this Resolution, and the following requirements must be met:~~ **~~(Wording given by Resolution – RDC nº 208, of January 5, 2018) (Revoked by Resolution – RDC nº 383, of May 12, 2020)~~**

~~a) The product must be regularized with ANVISA, upon arrival in the national territory;~~ **~~(Wording given by Resolution – RDC nº 208, of January 5, 2018) (~~Revoked by Resolution – RDC nº 383, of May 12, 2020)**

~~b) presentation by the importer of the document of its licensing by the competent health surveillance body, or Health Permit, with the State, District Federal or Municipal;~~ **~~(Wording given by Resolution – RDC nº 208, of January 5, 2018) (~~Revoked by Resolution – RDC nº 383, of May 12, 2020)**

~~c) The company must be regularized with ANVISA, regarding Authorization Special Operation (AE) for the activity of importing medicines subject to special control, under the terms of Ordinance SVS/MS nº 344, of May 12, 1998;~~ **~~(Wording given by Resolution – RDC nº 208, of January 5, 2018) (Revoked by Resolution – RDC nº 383, of May 12, 2020)~~**

~~d) declaration from the legal entity holding the regularization of the product, together with ANVISA authorizing the import, and must:~~ **~~(Wording given by Resolution – RDC nº 208, of January 5, 2018) (Revoked by Resolution – RD~~C nº 383, of May 12, 2020)**

~~i) be linked to 1 (one) single and exclusive legal entity, and the transfer of this authorization is prohibited;~~ **~~(Wording given by Resolution – RDC nº 208, of January 5, 2018) (Revoked by Resolution – RDC nº 383, of May~~ 12, 2020)**

~~ii) have legal validity and cannot be valid for more than 90 (ninety) days from its signature;~~ **~~(Wording given by Resolution – RDC nº 208, of January 5, 2018) (Revoked by Resolution – RDC nº 383, of May 12, 2020)~~**

~~iii) be signed by its legal guardian or legal representative, and by its technical manager; and~~ **~~(Wording given by Resolution – RDC nº 208, of January 5, 2018) (Revoked by Resolution – RDC nº 383, of May~~ 12, 2020)**

~~iv) express commitment to observance and compliance with the standards and procedures established by health legislation, as well as awareness of the penalties to which it will be subject, under the terms of Law no. 6,437, of August 20, 1977.~~ **~~(Wording given by Resolution – RDC no. 208, of January 5, 2018)~~**
(Revoked by Resolution – RDC nº 383, of May 12, 2020)

~~2. Imports of products purchased directly by public institutions that are part of the organizational structure of the Unified Health System will be excluded from the obligation referred to in subitem 1.1., item "b",~~ **~~(Repealed by Resolution –~~**
DRC nº 383, May 12, 2020)

~~3. Imports of medicines, special foods and medical products not regulated by ANVISA intended for clinical treatment, must undergo a prior opinion from the competent technical area and assessment and authorization by the ANVISA Collegiate Board.~~ **~~(Revoked by Resolution – RDC nº 383, of May 12, 2020)~~**

~~3.1. The import covered by this item must be supported by a technical report justifying the therapeutic or diagnostic indication, signed by the responsible professional;~~

~~3.1. The import referred to in this item must be subsidized by a technical-scientific report containing justification for the need for import; technical-scientific evidence based on official compendia that prove the effectiveness and safety of the medicine; and proof of registration of the medicine in the country of origin or in the country in which it is sold.~~ **~~(Wording given by Resolution – RDC nº 208, of January 5, 2018) (Revoked by Resolution – RDC nº 383, of May 12, 2020)~~**

~~3.1.1. Imports destined for a public institution that is part of the Unified Health System will be excluded from the provisions of the previous subitem, which must present a declaration justifying the importation signed by the Responsible Person or Legal Representative.~~ **~~(Revoked by Resolution – RDC nº 383, of~~ May 12, 2020)**

~~3.2. The import referred to in this item will take place in accordance with the provisions of Chapter XXXIX of these Regulations.~~ **~~(Revoked by~~ Resolution – RDC nº 383, of May 12, 2020)**

~~4. Any act of trade in the products referred to in this document will be prohibited.~~ ~~Chapter.~~ **(Revoked by Resolution – RDC nº 383, of May 12, 2020)**

CHAPTER X

INTERNATIONAL DONATION DESIGNED FOR QUALIFIED PHILANTHROPIC INSTITUTIONS

SECTION I

GENERAL PROVISIONS

1. The international donation referred to in this Chapter related to the import of goods or products belonging to the classes of medicines, foods, perfumes, cosmetics, personal hygiene products, sanitizing products, in vitro diagnostic products, medical products, used articles of clothing and Artifacts made of textile and synthetic materials, used, intended for legal entities, under public or private law, must undergo a favorable opinion from the competent health authority of ANVISA and meet the requirements established in health legislation.

1.1. They can only be the object of the international donation referred to in this Chapter the goods or products in the form of a finished product.

2. The request for an opinion from the competent health authority of ANVISA will be made by the legal entity governed by public or private law, recipient of the donation, prior to the shipment of the good or product abroad, as per Section I, Chapter III and Petition for Inspection Sanitary provided for in subitem 1.2., Chapter II of this Regulation, instructed with the documentation provided for in Chapter

2.1. The approval of import licensing registered with SISCOMEX and sanitary release of the good or product will occur at the customs clearance location of the good or product.

2.2. The exclusive import of used clothing items and artifacts made of used textile and synthetic materials will be exempt from pre-boarding requests.

2.3. Imports of goods and products by international donation intended to collaborate in the evaluation and development of research are exempt from the requirements of this item, as set out in the relevant Regulation.

3. The import of goods or products, referred to in this Chapter, regularized with ANVISA, by a person who does not have their regularization, will be subject to the presentation of a declaration by the legal entity holding the regularization of the product with ANVISA, authorizing import.

3.1 The declaration from the legal entity holding the regularization of the product, with ANVISA authorizing the import, will be presented in its original form and copy, for authentication, or previously authenticated, which will be retained, and must also:

i) be linked to a single and exclusive legal entity, and the transfer of this authorization is prohibited;

ii) have legal validity, including not being valid for more than 90 (ninety) days from its signature;

iii) be signed by its legal guardian or legal representative, and by its technical responsible, with notarized signature;

iv) express the commitment to observe and comply with the standards and procedures established by health legislation, as well as being aware of the penalties to which it will be subject, under the terms of Law No. 6,437, of August 20, 1977

4. Failure to comply with the requirements set out in this Chapter, within the period established by the health authority, will result in the impediment of the nationalization of goods or products under international donation.

5. The import by means of international donation of goods or products under health surveillance with the primary packaging damaged or in a state of "in use" and used medical products, including clothing for hospital use, will be prohibited.

6. The discovery in physical inspection or documentary analysis upon arrival in the national territory of a product that does not comply with the information provided by the import registration and inspection and release petition will result in the adoption of restrictive or punitive measures.

SECTION II

CLEANING AND SANITIZING CLOTHING OR TEXTILE ARTIFACTS AND SYNTHETICS

7. Used clothing items and artifacts made of textile and synthetic materials must be clean and sanitized upon arrival in the national territory.

7.1. At the discretion of the health authority, hygiene procedures may be required to be carried out in the national territory in an establishment intended for the proposed purpose, and import licensing at SISCOMEX may be granted with reservations, and the exit of the good or product from the customs area may be authorized, subjecting the importer to the Term of Custody and Responsibility.

7.2. The reservation referred to in the previous sub-item must be registered in the field referring to the status of the Import License in SISCOMEX with the following text: "GOOD OR PRODUCT UNDER SANITARY REQUIREMENTS. RELEASE FOR DISPLAY OR DELIVERY FOR CONSUMPTION SHALL BE TAKEN BY MANIFESTATION EXPRESS FROM THE HEALTH AUTHORITY".

7.3. The importer of goods or products must present to the health authority a document issued by a company providing cleaning and hygiene services, which proves its provision, containing a description of the methodology used, as well as the products used.

7.4. The release of goods or products for display or delivery for consumption human health will only occur after sanitary requirements have been met.

CHAPTER XI

INTERNATIONAL DONATION OF GOODS AND PRODUCTS

Pre-boarding documentation:

1- Petition for Inspection and relevant health clearance;

2- Import Licensing, copy;

3- Union Collection Guide, as provided for in relevant health legislation.

4- Information about the regularization of the product in the National System of Health Surveillance, when applicable;

5- Declaration granted by the holder of the document regularizing the product at ANVISA, authorizing the outsourcing of imports, when applicable;

6- List of imported goods and products, when dealing with donations belonging to the classes of medicines, medical products, in vitro diagnostic products and foods, and must be informed, for each commercial name, its respective class, category, presentation, date expiration date and the respective batch number(s).

7- Declaration, signed and notarized, from the legal entity responsible for the import in SISCOMEX, informing about the purpose of use and identification of the storage and/or distribution locations of the imported good or product, in the territory national.

- Post-shipment documentation:

1- Petition for Inspection and relevant health clearance;

2- Import Licensing, copy;

3- Authorization of access for physical inspection (IN SRF 206, of 25/09/2002, or technical standard that replaces it), when applicable;

4- Bill of Lading (AWB, BL, CTR), original and copy;

5- Certificate or document proving the hygiene of the good or product when it comes to clothing and clothing for personal use or used utensils;

6- Term of Custody and Responsibility, when applicable;

7-Term of Responsibility, signed and notarized, by the technical responsible of the Legal Entity, importer in SISCOMEX, assuming responsibility for any damage to the health of users, resulting from the use of imported goods or products, in the national territory;

8- List of imported goods or products, when dealing with donations belonging to the classes of medicines, medical products, in vitro diagnostic products and foods, and must be informed, for each commercial name, its respective class, category, presentation, date expiration date and the respective batch number(s).

CHAPTER XII

~~IMPORT BY INDIVIDUAL~~

~~SECTION I~~

~~GENERAL PROVISIONS~~

~~1. The import of finished products in original packaging under sanitary supervision, by an individual, for personal consumption, will be subject to approval prior to clearance by the sanitary authority.~~

~~1.1. Imports for personal consumption are considered to be the entry into the national territory of products in quantity and frequency compatible with the duration and~~

~~purpose of your stay and/or treatment, or as long as it does not constitute commerce or provision of services to third parties.~~

~~1.2. The import of products referred to in this item with the primary and/or secondary packaging tampered with and/or damaged, or in "used condition".~~

~~1.3. Products included in accompanied baggage are excluded from the provisions of the previous subitem, in which the natural person, the traveler, is carrying use.~~

~~2. The import of goods and products belonging to the classes of medical products intended for the provision of services to third parties must be carried out through SISCOMEX.~~

~~3. Considering the international epidemiological context, human, animal or plant, or the implementation of public health programs related to the sanitary control of goods or products and companies involved in all stages of production, distribution, import, transport and storage of goods and products under health surveillance, their import or entry in any capacity into the national territory by an individual may be prohibited on an emergency and transitional basis.~~

~~SECTION II~~

~~THE IMPORT FOR PERSONAL CONSUMPTION OF MEDICINES AND FOOD, FOR CONTINUOUS USE OR SPECIAL NUTRITIONAL, MEDICAL PRODUCTS AND PRODUCTS FOR IN VITRO DIAGNOSIS.~~

~~4. The import of goods and products belonging to the classes of medicines and foods for continuous or special nutritional use, as well as products for in vitro diagnosis and medical products, intended for personal consumption will only be authorized upon presentation to the health authority of prescription of the relevant professional, who will be retained if the following conditions are met:~~

~~a) be written in the official vernacular, or, if in another language, a translation signed by a signatory duly identified through name, address and Individual Taxpayer Registration Number - CPF may be requested.~~

~~b) contain information regarding the patient's name and address, dosage or method of use of the item or product, indicating the periodicity of treatment and limited to a maximum of 180 days, in the case of continuous use;~~

~~c) contain the date and signature of the professional, their home or professional address.~~

~~4.1. When issued by a professional working in Brazil, the prescription must also contain information regarding the registration number with the Professional Council.~~

4.2. The provisions of this Chapter include the import of medicines subject to special control, based on substances from the "C1" and "C4" lists referred to in Ordinance SVS/MS nº 344, of 1998 and its updates, must be accompanied by medical prescription and tax document proving its acquisition, in quantity for individual consumption and under the conditions set out in the paragraphs of item 4.

4.2.2. The transit mode of passage, accompanied baggage, is exempt from presenting proof of acquisition.

4.3. The import of products for personal consumption must be compatible with the prescription, including the presentation of the prescribed product.

SECTION III

IMPORTATION FOR PERSONAL CONSUMPTION OF COSMETICS, PERSONAL HYGIENE PRODUCTS, PERFUMES, SANITIZERS AND FOOD.

5. The import of products belonging to the classes of cosmetics, personal hygiene products, perfumes, sanitizers and foods intended for personal consumption will only be carried out through physical inspection at the discretion of the health authority and if the following conditions are met:

a) present themselves in accordance with the provisions of paragraphs b, c and d, item 1, Capítulo V;

b) in compatibility with the circumstances of the trip and/or in a quantity, nature or variety that do not allow the assumption of import for commercial or industrial purposes.

SECTION IV

THE IMPORT OF MEDICAL PRODUCTS TO PROVIDE SERVICES TO THE 3RD

6. The importation by an individual of medical products intended for the provision of services, at the finished product stage, must be carried out through SISCOMEX and the Petition for Inspection and Sanitary Release referred to in subitem 1.2 of Chapter II, of these Regulations, duly completed;

6.1 Additionally, the following documents must be presented:

a) declaration signed by the importer, containing:

i) registration number with the Professional Class Council;

ii) address of the place where the product is installed or stored;

~~iii) product specifications, such as commercial name, name complement, its identifying code and manufacturer, name of the holder of its regularization with ANVISA and respective regularization registration number;~~

~~iv) commitment to administrative, civil and criminal liability for direct or indirect damage to individual, collective and public health resulting from the use of the good and product;~~

~~v) commitment not to sell the product.~~

~~b) license of the establishment, or health permit, or corresponding official document issued by the competent authority, of the place where the product will be installed or stored, when it is not used, which must be presented in its original form and a copy, for authentication, which will be retained.~~

~~7. When importing goods and products under registration, registration or model authorization with ANVISA, a declaration must be presented by the legal entity holding the product regularization document with ANVISA authorizing the import.~~

~~7.1. The declaration referred to in the previous item must be presented in its original form and copy, for authentication, or previously authenticated, which will be retained, and must also:~~

~~a) be linked to a single and exclusive legal entity, and the transfer of this authorization is prohibited;~~

~~b) be signed by its legal guardian or legal representative, and by its technical responsible, with notarized signature;~~

~~8. The Import referred to in this Section of goods and products under registration, registration or model authorization with ANVISA, will be authorized and granted by the health authority in office at the place of customs clearance upon compliance with the provisions of item 7 and satisfactory health inspection .~~

~~9. Changing the purpose of importing and selling products will be prohibited.~~
~~goods and products covered by this Chapter.~~

Chapter XII

Import by Individual

(Wording given by Resolution - RDC nº 28, of June 28, 2011)

1. The importation of finished products belonging to the classes of medicines, health products, food, sanitizing products, cosmetics,

personal hygiene products and perfumes, made by an individual and intended for their own use. **(Wording given by Resolution - RDC nº 28, of June 28, 2011)**

1.1 The provisions of this item include goods and products included in the accompanied or unaccompanied luggage of a traveler coming from abroad. **(Wording given by Resolution - RDC nº 28, of June 28, 2011)**

1.2 It is considered for own use the import of products in quantity and frequency compatible with the duration and purpose of processing, or that does not characterize commerce or provision of services to third parties. **(Wording given by Resolution - RDC nº 28, of June 28, 2011)**

1.3 The import of medicines based on substances listed in Ordinance SVS/MS No. 344, of May 12, 1998, and its updates, is excluded from the provisions of this item, which must comply with the provisions of the Collegiate Board Resolution - RDC No. 63, of September 9, 2008, and its updates, and also medicines with use restrictions described in specific regulations. **(Wording given by Resolution - RDC nº 28, of June 28, 2011)**

2. The importation by an individual of health products intended for the provision of services to third parties will be carried out exclusively by SISCOMEX and must meet the requirements set out in the corresponding import procedures provided for in Chapter XXXIX of the Collegiate Board Resolution - RDC No. 81, of November 5, 2008. **(Wording given by Resolution - RDC nº 28, of June 28, 2011)**

3. Entry into the national territory will be prohibited for: **(Wording given by Resolution - RDC nº 28, of June 28, 2011)**

3.1. cells and tissues intended for therapeutic purposes not authorized by the competent technical area of ANVISA; and **(Wording given by Resolution - RDC nº 28, of June 28, 2011)**

3.2. products without identification in their original primary and/or secondary packaging, imported by express, postal or international air parcel. (NR) **(Wording given by Resolution - RDC nº 28, of June 28, 2011)**

CHAPTER XIII

APPLICATION FOR RECOGNITION OF PURPOSE FOR TAX EXEMPTION IMPORT FOR MEDICAL-HOSPITAL MATERIALS

1. For the purposes of characterizing the compatibility of the nature, quality and quantity of the good or product with the essential purposes of the importer for exemption from import tax, under the terms of Decree No. 4,543, of 2002, it will be up to the

importer submits a request to the competent health authority at ANVISA headquarters.

1.1. The application referred to in this item must be completed in accordance with the Petition for Recognition of Purpose for Exemption from Import Tax, in accordance with subitem 1.2 of Chapter II, of these Regulations, and must be supported by the documentation described in Chapter XIV, of these Regulations. .

1.2. For the purposes of this Chapter, medical-hospital material will be considered to be goods or products under health surveillance, intended for the prevention, diagnosis, treatment and rehabilitation of human, individual or collective health.

2. The import of goods or products referred to in this Chapter by a person who does not have their regularization with ANVISA, will be subject to the presentation of authorization from the legal entity holding the regularization of the good or product with ANVISA, for each import. .

2.1 The declaration from the legal entity holding the regularization of the product, with ANVISA authorizing the import, will be presented in its original form and copy, for authentication, or previously authenticated, which will be retained, and must also:

i) be linked to a single and exclusive legal entity, and the transfer of this authorization is prohibited;

ii) have legal validity, including not being valid for more than 90 (ninety) days from its signature;

iii) be signed by its legal guardian or legal representative, and by its technical responsible, with notarized signature;

iv) express the commitment to observe and comply with the standards and procedures established by health legislation, as well as being aware of the penalties to which it will be subject, under the terms of Law No. 6,437, of August 20, 1977.

3. When examining the application, the health authority may request
requirements to the importer for a specific period of time for compliance.

3.1. Failure to comply with the requirements referred to in this item, within the established period, will result in the importer rejecting the application for exemption from import tax.

4. The requesting importer, after a favorable opinion from ANVISA for exemption from tax, will be responsible for complying with and enforcing the declared purpose of the good or product, when used or displayed in the national territory.

CHAPTER XIV

INSTRUCTION DOCUMENTATION OF THE APPLICATION FOR RECOGNITION OF PURPOSE FOR IMPORT TAX EXEMPTION

1. Petition for Inspection and Sanitary Release of Imported Goods and Products - ANVISA;

2. Request for recognition of purpose for Tax Exemption
Importation of Medical-Hospital material under the terms of this Regulation;

3. Union Collection Guide from the National Treasury Secretariat, as per provided for in relevant health legislation;

4. Import Licensing or Simplified Import Licensing Extract, updated (copy);

5. Information about the regularization of the product with ANVISA, when applicable;

6. Declaration given by the holder of the document regularizing the product at ANVISA, authorizing import by third parties, when applicable;

7. Declaration signed by the Company's legal representative, undertaking that the imported good or product will be for the exclusive use of the importing institution, indicating the location(s) of installation, use or consumption of the good or product, in which case fit;

8. Importer's power of attorney with delegation of powers to ANVISA, as applicable:

a) petition for inspection and health clearance;

b) monitoring of the technical analysis stages for the purposes of granting the purpose recognition letter for import tax exemption;

c) document signed by the legal representative of the interested party with a nominal list of the employees legally qualified to execute the powers delegated in the power of attorney instrument referred to in the previous paragraph.

d) awareness of legal terms and other related documents;

e) presentation of means of defense, such as filing of appeals.

9. Specify the name and full address of the customs area where customs clearance will take place.

~~CHAPTER XV~~

~~LABELING OF IMPORTED GOODS OR PRODUCTS - FINISHED PRODUCT~~

~~1. Labeling will be permitted in the national territory, in accordance with the relevant legislation of imported products formally regularized with the National Health Surveillance System.~~

~~1.1. The delivery for consumption of imported products with identification or labeling in a foreign language will be prohibited, except for imports for non-commercial purposes referred to in Chapters IX, X, XII, XIX, XX and XXI of these Regulations.~~

~~1.2. The products referred to in this item, when exposed or delivered for consumption, must be labeled, sealed or under a security seal, when required by relevant health legislation, and with the information approved by the competent health authority, upon regularization in the System. National Health Surveillance.~~

~~1.3. The authority referred to in this item will not exempt the importer from presenting the following information on the foreign language label of its packaging, primary and/or secondary, upon entry into the national territory.~~

~~a) commercial name, in use abroad;~~

~~b) name of the manufacturer and place of manufacture;~~

~~c) batch or batch number or code;~~

~~d) date of manufacture, when required by relevant health legislation;~~

~~e) expiration date or expiration date, when applicable.~~

~~1.4. For the purposes of the provisions of the previous item, the health authority may be required to present the respective translation of the label of the imported good or product, signed by the technical responsible and the responsible or legal representative of the company holding the regularization of the product with the National System of Health Surveillance.~~

~~1.4.1 In the case of food, the translation of the label may be signed by the responsible or legal representative of the importing company.~~

~~1.5. In the event of the absence of the information referred to in subitem 1.3, item "d", on the label of goods and products belonging to the classes of cosmetics, perfumes and personal hygiene products, the importer will be obliged to present it to the health authority in office at the location of clearance of the good or product in the national territory, declaration signed by the technical manager of the importing company, informing the date of manufacture of the batch or departure for each imported product.~~

~~1.6. In the case of importing goods and products belonging to the classes of cosmetics and personal hygiene products, the importer will be exempt from complying with the provisions of subitem 1.3, item "e".~~

~~1.7. In the case of the absence, on the label in a foreign language of an imported product belonging to the class of in vitro diagnostic products, of the information referred to in subitem 1.3, item "d", the importer will be obliged to present it to the health authority in office at the location clearance in the national territory, declaration signed by the technical responsible of the importing company informing the date of manufacture of the batch or batch for each imported product or analytical quality control report, per batch or batch for each imported product, signed by the technical responsible of the company importer, including information regarding the date of manufacture.~~

~~2. The import of a product with a label in Portuguese that does not comply with the provisions of health legislation may be subject to import licensing at SISCOMEX with reservations, and its departure from the authorized customs area, subject to the importer being subject to a Term of Custody and Responsibility .~~

~~2.1. The reservation referred to in this item must be registered in the field referring to the status of the Import License in SISCOMEX with the following text: "PRODUCT UNDER SANITARY REQUIREMENTS. RELEASE FOR INDUSTRIALIZATION, DISPLAY FOR SALE OR DELIVERY FOR CONSUMPTION WILL BE TAKEN THROUGH EXPRESS MANIFESTATION FROM THE HEALTH AUTHORITY".~~

CHAPTER XV

LABELING OF IMPORTED GOODS OR PRODUCTS - FINISHED PRODUCT

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

1. The labeling of imported products will be permitted in national territory, subject to the relevant legislation. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

1.1. The delivery for consumption of imported products with identification or labeling in a foreign language will be prohibited, except for imports for non-commercial purposes referred to in Chapters IX, X, XII, XIX, XX and XXI of this Resolution.
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

1.2. The products covered by this item, when displayed or delivered for consumption, must be labeled in accordance with the health legislation relevant to the product class. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2. The primary or secondary or transport packaging must contain the following minimum information upon entry into the national territory, according to the product class to which it belongs: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.1 Food: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Commercial name in use abroad; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Name of the manufacturer and place of manufacture; **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

c) Lot number; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

d) Expiry date. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.2 Cosmetics / Perfumes / Hygiene Products: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Commercial name in use abroad; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Country of manufacture; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) batch number or code. **(Wording given by Resolution – RDC nº 208, of 5 January 2018)**

2.3 Sanitizing: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Commercial name in use abroad; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Name of the manufacturer and place of manufacture; **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

c) Lot number; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

d) Expiry date. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.4 Health Products: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Commercial name in use abroad; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Name of the manufacturer and place of manufacture; **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

c) Lot number or code or part number; **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

d) Date of manufacture; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

e) Expiry date. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.5 In vitro diagnostic products: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Commercial name in use abroad; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Name of the manufacturer and place of manufacture; **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

c) Lot number or code or part number; **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

d) Date of manufacture; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

e) Expiry date. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.6 Medicines: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Commercial name; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Name of the manufacturer and place of manufacture; **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

c) batch or batch number or code; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

d) date of manufacture; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

e) expiration date **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

3. For the purposes of the provisions of item 2 of this Chapter, the health authority may require the presentation of the respective translation of the label of the imported good or product, signed by the technical responsible and the responsible or legal representative of the company holding the regularization of the product with to the National Health Surveillance System. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

3.1. In the case of food, the translation of the label may be signed by the responsible person or legal representative of the importing company. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

4. In the event of the absence, on the label in a foreign language of an imported product belonging to the class of in vitro diagnostic products, of the information referred to in subitem 2.5, item “d” of this Chapter, the importer will be obliged to present a declaration signed by the technical manager of the importing company, informing the date of manufacture of the batch or departure, for each imported product; or analytical quality control report, by batch or batch, for each imported product, including information regarding the date of manufacture. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

5. The import of a product with a label in Portuguese language that does not comply with the provisions of health legislation may result in approval, with reservations, of import licensing at SISCOMEX, as well as departure from the authorized customs area, subject to the importer being subject to a Term of Custody and Responsibility. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

5.1. The reservation referred to in item 5 of this Chapter must be registered in the field referring to the status of the Import License in SISCOMEX with the following text: “PRODUCT UNDER SANITARY REQUIREMENT. RELEASE FOR INDUSTRIALIZATION, EXHIBITION FOR SALE OR DELIVERY FOR CONSUMPTION SHALL TAKE PLACE THROUGH EXPRESS REPORT FROM THE HEALTH AUTHORITY”. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XVI

PRODUCT IN INTERMEDIATE STAGE OF PRODUCTION PROCESS

SECTION I

OF MEDICINES

1. Products belonging to the class of medicines, in intermediate stages of their production or manufacturing process, semi-finished and bulk product stages, devoid of primary packaging, must be submitted to the technical department of the importing company, located in the national territory , for laboratory tests necessary to prove its nature, identity and quality in these stages of production or manufacturing.

1.1. The import of these products must be carried out through SISCOMEX - Import Module.

1.2. Under the terms of Chapter VI of these Regulations, the outsourcing of the import of products referred to in this Section will be permitted.

1.2.1 Quality control of the products covered by this item may be carried out by official institutes or laboratories, through agreements or contracts.

1.3. Excluded from the requirements set out in this Regulation are the presentation of laboratory tests necessary to prove their nature, identity and quality in these stages of production or manufacturing, and imports of medicines for clinical research purposes into the national territory.

2. The import referred to in this Section will only be carried out upon approval of an Import Licensing with SISCOMEX with reservations, and its departure from the customs area authorized through subjection to the Term of Custody and Responsibility, per batch, registered in the field referring to the text of the import licensing status: "PRODUCT UNDER SANITARY REQUIREMENT. RELEASE TO INDUSTRIALIZATION, DISPLAY FOR SALE OR DELIVERY FOR CONSUMPTION WILL TAKE PLACE THROUGH EXPRESS STATEMENT FROM THE HEALTH AUTHORITY". **(Requirement suspended by Resolution - RDC nº 48, of August 31, 2012)**

2.1. The health requirement covered by this item will be, among others, the obligation to present an analytical quality control report complete with tests in accordance with the analytical methodology of products belonging to the class of medicines, in intermediate stages of their production process. or manufacturing, semi-finished and bulk product stages devoid of primary packaging. **(Requirement suspended by Resolution - RDC nº 48, of August 31, 2012)**

2.2. The Term of Custody and Responsibility referred to in this item, in the case of outsourced imports, must be submitted to the health authority in office in the

premises bonded by the company holding the drug registration with ANVISA, signed by the Legal Representative and Technical Responsible Person. **(Requirement suspended by Resolution - RDC nº 48, of August 31, 2012)**

2.2.1. The removal of samples from products imported under the Term of Custody and Responsibility referred to in this Section will be authorized under this item. **(Requirement suspended by Resolution - RDC nº 48, of August 31, 2012)**

2.2.2. The withdrawal referred to in this subitem will be limited to the necessary quantities and exclusive purpose for laboratory analysis or preparation of the Quality Control Report. **(Requirement suspended by Resolution - RDC nº 48, of August 31, 2012)**

2.2.3. The company holding the product registration, including in outsourced imports, will be obliged to keep on file the information relating to the product units removed for the purposes of laboratory analysis and preparation of the Quality Control Report, which must contain the registration of these units.
(Requirement suspended by Resolution - RDC nº 48, of August 31, 2012)

3. The release of the product under the Term of Custody and Responsibility will be carried out by the health authority, in office at the place of clearance, upon satisfaction of the health requirements through a satisfactory technical analysis of the conclusive laboratory report presented by the importer. **(Requirement suspended by Resolution - RDC nº 48, of August 31, 2012)**

3.1. For the purposes of the technical analysis referred to in this item, the company holding the product regularization document with ANVISA must present in the analytical quality control report carried out in the national territory, the types of tests and analytical results compatible with those reported by the manufacturer and must be signed by the company's technical manager. **(Requirement suspended by Resolution - RDC nº 48, of August 31, 2012)**

SECTION II

OF FOOD, COSMETICS, PERFUMES, PERSONAL HYGIENE PRODUCTS, SANITIZERS, MEDICAL PRODUCTS AND IN VITRO DIAGNOSTIC PRODUCTS

4. Products belonging to the classes of food, perfumes, cosmetics, hygiene products, sanitizing products, in vitro diagnostic products, medical products, in an intermediate stage of their production or manufacturing process, semi-elaborated and bulk product stages, They must be submitted to the technical department of the importing company located in the national territory, for laboratory tests, necessary to prove their nature, identity and quality.

4.1. Quality control of the goods or products referred to in this Section may be carried out by official institutes or laboratories, through agreements or contracts.

5. The competent federal, state or municipal health authority will be responsible for carrying out the original, complementary or concurrent health inspection referred to in this Section, in order to guarantee the maintenance of its nature, identity and quality upon exposure or consumption.

CHAPTER XVII

QUALITY CONTROL ANALYTICAL REPORT WITH IRREGULARITY

1. The import of products in the form of raw material, semi-finished product, bulk product or finished product, whose Analytical Quality Control Report per batch or batch required in this Regulation, presents an unsatisfactory analytical result, partial or total, or with records of information that do not comply with the documentation presented, their health release will not be authorized.

1.1. Non-sanitary release will apply to imports in other modalities provided for in Chapter III of this Regulation, subjecting the products to interdiction in the customs area.

CHAPTER XVIII

REFURBISHED OR USED MEDICAL PRODUCTS AND RADIOACTIVE SOURCES SEALED

~~SECTION I~~

~~GENERAL PROVISIONS~~

~~1. The import by companies of goods or products belonging to the classes of medical products, used and reconditioned, components and accessories, must comply with the provisions of relevant health legislation.~~

~~SECTION II~~

REFURBISHED MEDICAL PRODUCTS

~~2. The import of reconditioned medical products must be carried out through SISCOMEX, and the application and processing formalities will be met in accordance with Procedure No. 4.1, of Chapter XXXIX, of this Regulation and relevant health legislation.~~

~~3. The import of medical products reconditioned by a company that does not have regularization with ANVISA will be subject to the presentation of a declaration~~

~~of the legal entity holding the regularization of the good or product with ANVISA, authorizing the import.~~

~~3.1 The declaration from the legal entity holding the regularization of the product, with ANVISA authorizing the import, will be presented in its original form and copy, for authentication, or previously authenticated, which will be retained, and must also:~~

~~i) be linked to a single and exclusive legal entity, and the transfer of this authorization is prohibited;~~

~~ii) have legal validity, including not being valid for more than 90 (ninety) days from its signature;~~

~~iii) be signed by its legal guardian or legal representative, and by its technical responsible, with notarized signature;~~

~~iv) express the commitment to observe and comply with the standards and procedures established by health legislation, as well as being aware of the penalties to which it will be subject, under the terms of Law No. 6,437, of August 20, 1977.~~

~~SECTION III~~

~~USED MEDICAL PRODUCTS~~

~~4. The import of used medical products will be prohibited.~~

~~4.1. Authorization for the importation by the company registered with ANVISA of a medical product used for reconditioning purposes into the national territory will be based on a conclusive and satisfactory opinion from the competent technical area of ANVISA at its headquarters.~~

~~SECTION IV~~

~~SEALED RADIOACTIVE SOURCES FOR USE IN HEALTHCARE SERVICES~~

~~5. The importer of sealed radioactive sources referred to in this Chapter, in addition to the requirements set out in Procedure 4.1 of Chapter XXXIX of this Regulation, must present, within 60 (sixty) days after the approval of the import license by the health authority, a signed declaration by the legal responsible and the technical responsible, in its original form and copy, for authentication or previously authenticated, which will be retained.~~

~~5.1. In compliance with the provisions of this Section, the NCM subject to to complementary import sanitary control:~~

~~a) NCM code: 2844.40.20,~~

~~a.1) Description: Cobalt 60;~~

~~b) NCM code: 2844.40.90,~~

~~b.1) Description: Others;~~

~~b.2) Highlight Description - NCM: Radium (Ra-226), Cesium (Cs-137), Iodine (I- 125), Gold (Au-198), Strontium (Sr-90), Iridium (Ir-192) and other sealed sources for use in health services;~~

~~c) NCM Code: 9022.2~~

~~c.1) Description: Devices that use alpha, beta or gamma radiation, including for medical, surgical, dental or veterinary uses, including radiophotography or radiotherapy devices.~~

~~5.2. The following information must be included in the declaration covered by this item:~~

~~a) source specifications: radionuclide, quantity and form;~~

~~b) purpose of using the source;~~

~~c) radionuclide activity: value and date of measurement.~~

~~d) destination of the source: Name of the institution, CNES number, full address of the location where it is installed.~~

~~5.3. The health authority in office at the location where customs clearance will take place must draw up a legal Notification Term to the importer and/or make information available on Siscomex guiding him to comply with the requirements referred to in this item, with regard to the imports referred to in this Section .~~

~~5.4. The Health Surveillance Coordination of Ports, Airports, Borders and Bonded Precincts in the States and Federal District must forward to the General Management of Ports, Airports, Borders and Customs Precincts, a bimonthly report, per importing company, containing the information presented.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XVIII

REFURBISHED OR USED MEDICAL PRODUCTS AND RADIOACTIVE SOURCES SEALED

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

SECTION I

GENERAL PROVISIONS

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

1. The import, by companies, of goods or products belonging to the classes of medical products, used and reconditioned, components and accessories, must comply with the provisions of relevant health legislation. **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

SECTION II

REFURBISHED MEDICAL PRODUCTS

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

2. The import of reconditioned medical products must be carried out through SISCOMEX, and the application and processing formalities will be met, in accordance with Procedure 4, of Chapter XXXIX of this Resolution and relevant health legislation. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

3. The import of refurbished medical products, by a company that does not hold regularization with ANVISA, will depend on the presentation of a declaration by the legal entity holding the regularization of the good or product with ANVISA, authorizing the import, and must: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) be linked to a single and exclusive legal entity, and the transfer of this authorization is prohibited; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) have legal validity, including not being valid for more than 90 (ninety) days from its signature; **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

c) be signed by its legal guardian or legal representative, and by its technical manager; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

d) express the commitment to observe and comply with the standards and procedures established by health legislation, as well as being aware of the penalties to which it will be subject, under the terms of Law no. 6,437, of August 20, 1977. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION III

USED MEDICAL PRODUCTS

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

4. The import of used medical products is prohibited. **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

4.1. Authorization for the import, by the company holding the respective registration with ANVISA, of a used medical product, for reconditioning purposes in the national territory, will be based on a conclusive and satisfactory opinion from the competent technical area of ANVISA at its headquarters. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION IV

SEALED RADIOACTIVE SOURCES FOR USE IN HEALTHCARE SERVICES

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

5. The importer of sealed radioactive sources referred to in this Chapter, in addition to the requirements set out in Procedure 4 of Chapter XXXIX of this Resolution, must present, within 60 (sixty) days from the approval, by the health authority, of the import licensing , declaration, signed by the legal responsible and the technical responsible, which contains the following information: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) source specifications: radionuclide, quantity and form; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) purpose of using the source; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) radionuclide activity: measurement value and date; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

d) destination of the source: name of the institution, CNES number, full address of the location where it is installed. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

5.1. The health authority must draw up a legal notice to the importer and/or make information available on Siscomex guiding him to the

compliance with the requirements referred to in item 5 of this Section. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

6. In compliance with the provisions of this Section, the NCMs subject to complementary import sanitary control are defined: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) NCM Code: 2844.40.20, **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a.1) Description: Cobalt 60; **(Wording given by Resolution – RDC nº 208, of 5 January 2018)**

b) NCM Code: 2844.40.90, **(Wording given by Resolution – RDC nº 208, January 5, 2018)**

b.1) Description: Others; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b.2) Highlight Description - NCM: Radium (Ra-226), Cesium (Cs 137), Iodine (I-125), Gold (Au-198), Strontium (Sr-90), Iridium (Ir-192) and other sealed sources for use in health services; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) NCM Code: 9022.2, **(Wording given by Resolution – RDC nº 208, of 5 January 2018)**

c.1) Description: Devices that use alpha, beta or gamma radiation, including for medical, surgical, dental or veterinary uses, including radiophotography or radiotherapy devices. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

CHAPTER XIX

~~IMPORT OF MATERIALS FOR SCIENTIFIC RESEARCH OF HEALTH INTEREST~~

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~SECTION I~~

~~GENERAL PROVISIONS~~

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~1. The import of biological products under sanitary surveillance intended for scientific research of sanitary interest, by a researcher or research entity not accredited by the CNPq, must undergo an express and favorable statement from the competent sanitary authority of ANVISA, prior to its clearance, at the~~

National territory. (Revoked by Resolution – RDC nº 172, of September 8, 2017)

1.1. The import referred to in this Chapter must be requested through a Petition for Inspection and Sanitary Release provided for in Chapter II, item 1.2, and instructed in accordance with the relevant Term of Responsibility. (Revoked by Resolution – RDC nº 172, of September 8, 2017)

2. Mandatory sanitary requirements will be established for the approval and sanitary release of materials referred to in this Chapter to comply with the packaging, transport and storage standards informed, where appropriate, by their manufacturer or supplier and by the relevant sanitary legislation. (Revoked by Resolution – RDC nº 172, of September 8, 2017)

3. The import of materials by individuals linked to the teaching and research institution, not accredited by the CNPq, must comply with the provisions of this Chapter.
(Revoked by Resolution – RDC nº 172, of September 8, 2017)

4. The import of biological or environmental samples intended for epidemiological or environmental laboratory diagnosis in laboratories that are part of the National System of Public Health Laboratories or for the evaluation and development of the National Public Health Program will be subject to prior approval upon shipment. abroad, from the competent body of the Ministry of Health. (Revoked by Resolution – RDC nº 172, of September 8, 2017)

5 Material imported by an individual or legal entity direct recipient of the research will be done through SISCOMEX, express shipment, postal shipment or Simplified Import Declaration - non-electronic DSI, subject to prior customs clearance for health inspection, by competent health authority of ANVISA. (Revoked by Resolution – RDC nº 172, of September 8, 2017)

5.1. The import referred to in this item will be exempt from the prior obligation of authorization for boarding abroad, except when set out in Procedures nº 1, nº 1-A, and nº 3, of Chapter XXXIX of these Regulations, and must be imported mandatorily by through SISCOMEX. (Revoked by Resolution – RDC nº 172, of September 8, 2017)

SECTION II

THE MATERIAL OBJECT OF SCIENTIFIC RESEARCH OF HEALTH INTEREST

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

6. The import referred to in this Section will take place in addition to the provisions of item 1.1. of this Chapter, the presentation of the Term of Responsibility contained in the Chapter

~~XIX-A, of these Regulations, which must be presented with notarized signatures. (Revoked by Resolution~~ – RDC nº 172, of September 8, 2017)

~~SECTION III~~

~~MATERIAL, NOT THE OBJECT OF SCIENTIFIC RESEARCH, IMPORTED FOR THE PURPOSES OF MONITORING, EVALUATING OR DEVELOPING SCIENTIFIC RESEARCH OF~~ HEALTH INTEREST.

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~7. The import of a product under health surveillance, intended for the monitoring, evaluation or development of scientific research of health interest, must occur through Import Licensing at SISCOMEX, subject to prior customs clearance for health inspection, by the competent health authority. from ANVISA. (Revoked by Resolution – RDC nº 172, of September 8, 2017)~~

~~8. The import referred to in this Section will take place in addition to the provisions of item 1.1. of this Chapter, the presentation of the Term of Responsibility contained in Chapter XIX-B, of these Regulations, which must be presented with a notarized signature. (Revoked by Resolution – RDC nº~~ 172, of September 8, 2017)

~~Subsection~~ I

~~Of Products Not Regularized with the National Health Surveillance System –~~ SNVS

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~9. The import of products belonging to the classes of medical products and in vitro diagnostic products, not regularized by ANVISA, linked to the monitoring and evaluation of the development of scientific research of health interest, will take place through SISCOMEX, express shipment or postal shipment and must submit to a conclusive and satisfactory technical opinion from the competent technical area of ANVISA at its headquarters, regarding the Import authorization.~~

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~10. In vitro diagnostic products that are not intended for diagnosis in human samples and that are used exclusively in scientific research are exempt from the opinion referred to in the item above. (Revoked by Resolution – RDC nº 172, of September 8,~~ 2017)

~~10.1. The import referred to in this item will be exempt from the prior obligation of authorization for shipment abroad. (Revoke~~d by Resolution – RDC nº 172, of September 8, 2017)

~~**Subsection II**~~

~~**Of Products Regulated with the National Health Surveillance System – SNVS**~~

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~11. The import of goods and products under health surveillance regularized with the SNVS, intended for individuals or legal entities linked to the research institution, for the purposes of monitoring, evaluating and developing scientific research, will occur through SISCOMEX, express shipment or remittance postage, for products included in procedure 5 (five), of Chapter XXXIX of this Regulation and upon prior submission to customs clearance for health inspection, by the competent health authority of ANVISA~~ ~~**(Repealed by Resolution – RDC nº 172, of September 8 2017)**~~

~~11.1. The goods and products under health surveillance included in the other procedures, in Chapter XXXIX of this Regulation, must comply with the recommendations in the aforementioned procedures.~~ ~~**(Revoked by Resolution – RDC nº**~~ **172, of September 8, 2017)**

~~**CHAPTER XIX-A**~~

~~**STATEMENT OF RESPONSIBILITY**~~

~~**IMPORT LINKED TO SCIENTIFIC RESEARCH OF HEALTH INTEREST**~~

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~1 - The natural/legal person _____, declares that the product(s) listed below were/were imported, without commercial or industrial purposes and are intended exclusively for research scientific research of health interest in the national territory, in accordance with the provisions of the Technical Regulation for Health Surveillance of Imported Goods and Products.~~

~~Item~~	~~Name~~	~~Group or category to which you belong~~	~~Lot number or match~~	~~Amount~~
~~01~~	~~-~~	~~-~~	~~-~~	~~-~~
~~02~~	~~-~~	~~-~~	~~-~~	~~-~~

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~2 - Information related to imports:~~ ~~**(Revoked by Resolut**~~**ion – RDC nº 172, of September 8, 2017)**

~~a) the title and object of scientific research of health interest;~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~b) the name and full address of the sending institution;~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~c) the country of manufacture of the imported material;~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~d) the country of origin of the material that makes up the product imported;~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~e) the country of origin of the imported product;~~ **(Repealed by Resolution – DRC no 172, of 8 September 2017)**

~~f) the expiration date of the imported product, when available;~~ **(Repealed by Resolution – RDC nº 172, of September 8, 2017)**

~~g) complete address of the importer;~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~h) name and full address of the recipient institution,~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~i) full name and address of the place where the research will take place;~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~j) document number and identification of the competent official body that regularized the research, when applicable;~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~l) name and respective registration with the class council of the researcher at the institution responsible for the research;~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~m) valid health license or corresponding document, issued by the competent authority of the State, Municipality or Federal District, where the analytical laboratory is located, when it is a mandatory requirement contained in relevant legislation;~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~n) additional identification of the imported merchandise, when applicable.~~ **(Revoked by Resolution – RDC nº 172, of September 8, 2017)**

~~The undersigned assume health responsibility for damage to individual or collective health and the environment resulting from the change in the purpose of the product entering the national territory.~~

~~PROFESSIONAL RESPONSIBLE FOR THE RESEARCH LEGAL REPRESENTATIVE~~

~~CR No.~~

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~CHAPTER XIX-B~~

~~STATEMENT OF RESPONSIBILITY~~

~~IMPORTATION FOR THE PURPOSES OF MONITORING, EVALUATION AND DEVELOPMENT OF SCIENTIFIC RESEARCH OF HEALTH INTEREST.~~

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~The natural/legal person _____, declares that the product(s) listed below were/were imported, without commercial or industrial purposes and are intended, exclusively, for scientific research of health interest in the national territory, in accordance with the provisions of the Technical Regulation for Health Surveillance of Imported Goods and Products.~~

~~Item~~	~~Name~~	~~Group or category to which you belong~~	~~Lot number or match~~	~~Amount~~
~~1~~	0 -	-	-	-
~~2~~	0 -	-	-	-

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

~~The undersigned assume health responsibility for damage to individual or collective health and the environment resulting from the change in the purpose of the product entering the national territory.~~

~~PROFESSIONAL RESPONSIBLE FOR THE RESEARCH LEGAL REPRESENTATIVE~~

~~CR No.~~

(Revoked by Resolution – RDC nº 172, of September 8, 2017)

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XX

REFERENCE STANDARD AND REFERENCE MATERIAL OF BIOLOGICAL NATURE NO HUMAN, ENVIRONMENTAL, CHEMICAL AND PHYSICAL FOR PROFICIENCY TEST

~~1. The import of standard and reference material must be subject to inspection by the health authority in office at the place of clearance, upon presentation of a Petition for Sanitary Inspection and Release provided for in Chapter II, subitem 1.2, instructed by a Term of Responsibility contained in of Chapter XX of these Regulations.~~

1. The import of standard and reference material must be subject to inspection by the health authority, upon presentation of a Petition for Health Inspection and Release provided for in Chapter II, subitem 1.2, instructed by the Term of Responsibility contained in Chapter XX, of this Resolution . **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

1.1. The import of standards and reference material for proficiency testing purposes will not be permitted, with the validity period expiring within the next 30 (thirty) days from its health authorization, as applicable.

1.2. The imports referred to in this Chapter will take place through SISCOMEX and Express Shipping import modalities.

1.3. The import referred to in this Chapter will be exempt from authorization for shipment abroad.

~~1.3.1. Imports of goods and products that integrate procedures 1, 1A, 3 and 6, of Chapter XXXIX.~~

1.3.1. Imports of goods and products that are part of procedures 1 and 1A of Chapter XXXIX are exempt from the provisions of this subsection. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

~~1.4. The Liability Term, of Chapter XX-A that this Chapter deals with It must be presented with signature recognition at a notary's office.~~

1.4. The Term of Responsibility, from Chapter XX-A, referred to in this Chapter, must be presented with the signature of the legal representative and the technical responsible. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

1.4.1. Signatories authorized by those responsible for managing the National System of Public Health Laboratories will be exempt from the requirement for signature recognition at a notary's office.

1.5. It will be prohibited to change the purpose for which the importation is intended deals with this Chapter.

CHAPTER XX-A

STATEMENT OF RESPONSIBILITY

STANDARD AND REFERENCE MATERIAL FOR PROFICIENCY TEST

The Company _____declares that the material(s):

Item	Identification of material under import	No. of units	Specification of the type(s) of analysis(ies)
01			
02			

It is intended exclusively for the purpose identified above and presents the following additional information:

a) the name and full address of the sending institution;

b) the country of manufacture of the imported material;

c) the country(ies) of origin of the material that makes up the imported material;

d) complete address of the importer;

e) name and full address of the recipient institution,

f) additional identification of the imported material, if applicable.

The undersigned assume health responsibility for damage to individual or collective health and the environment resulting from the change in the purpose of the product entering the national territory.

_____ _____

TECHNICAL MANAGER LEGAL REPRESENTATIVE

CR No.

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XXI

PRODUCT NOT REGULARIZED IN THE NATIONAL HEALTH SURVEILLANCE SYSTEM - SNVS - FOR REGISTRATION PURPOSES, INTENDED FOR MARKET RESEARCH, ANALYSIS LABORATORY, QUALITY CONTROL TESTS, PACKAGING EVALUATION OR EQUIPMENT LABELING AND TESTING

SECTION I =

OF MEDICINES

1. The import of product samples in the form of finished products or in bulk, belonging to the class of non-regularized medicines that contain in their composition substance(s) without established proof of safety and efficacy, intended for analysis for registration purposes, testing quality control, stability studies, bioequivalence and pharmaceutical equivalence or even tests of equipment participating in the manufacturing or laboratory process, must undergo authorization for shipment at Import Licensing - LI, by the competent technical area of the General Port Management, Airports, Borders and Customs Precincts - GGPAF, at its headquarters at ANVISA, upon presentation of a Petition for Inspection and Sanitary Release provided for in Chapter II, subitem 1.2.

1.1 - The provisions of this item will include the raw materials and active principles included in the formulations of these medicines in the technical analysis phase for registration with ANVISA, intended exclusively for carrying out quality control tests, in an analytical laboratory installed in the territory national.

1. The import of samples of finished products, in bulk or raw material, belonging to the class of medicines not regulated by ANVISA, which contain in their composition a substance without established proof of safety and efficacy, intended for testing, will have a Shipping Authorization analyzed and granted by the health authority, at the customs clearance location, upon presentation of the Petition for Health Inspection and Release. (NR) **(Wording given by Resolution - DRC nº 28, from June 28 of 2011)**

2. The import of samples of non-regularized medicines whose composition includes active substances with established proof of safety and efficacy, must meet the sanitary requirements set out in procedures 1, 1A, 2, 2A, 2B, 2C, 3, 5.3 and 6, in as applicable, in Chapter XXXIX.

2.1. Documents relating to the regularization of the medicine before ANVISA, provided for in the procedures of Chapter XXXIX, are excluded from the provisions of this item.

~~3. The approval of the Import Licensing and the sanitary release will take place in accordance with the provisions of Chapter XXXIX of these Regulations, by the sanitary authority in office at the place of clearance of the product.~~

~~4. The import referred to in this section must be in a quantity compatible with the stated purpose.~~

~~5. The importation of medicines not regulated by ANVISA, intended for market research.~~

~~**SECTION II**~~

MEDICAL PRODUCTS AND IN VITRO DIAGNOSTIC PRODUCTS

~~6. The import of product samples in the form of finished products belonging to the class of medical products and in vitro diagnostic products, not regularized by ANVISA, intended for analysis for registration, teaching or quality control testing purposes must be submitted the approval of the Import Licensing - LI, by the health authority at the place of clearance, after a conclusive and satisfactory opinion from the competent technical area of ANVISA, at its headquarters, through the presentation of a Petition for Inspection and Sanitary Release provided for in Chapter II, subitem 1.2.~~

~~6.1. The import of the product will be exempt from shipping authorization~~ not external

~~6 - The import of samples of finished products, belonging to the class of health products not regularized by ANVISA, intended for testing, must be subject to analysis and approval of Import Licensing by the health authority, at the customs clearance location, upon presentation of Petition for Inspection and Health Release. (NR)~~ **~~(Wording given by Resolution - RDC nº 28, of June 28, 2011)~~**

~~7. Commercialization and change of purpose informed in the procedure for import referred to in this Section.~~

~~**SECTION III**~~

OF SANITIZERS

~~8. The import of product samples in the form of finished products belonging to the class of household sanitizers, not regularized with ANVISA, and which are not expressly prohibited in the national territory, intended for analysis for registration purposes, quality control testing, proficiency, development of new products or equipment participating in the manufacturing or laboratory process must be subject to inspection by the health authority in the~~

~~place of clearance of the product, upon presentation of a Petition for Inspection and Sanitary Release provided for in Chapter II, subitem 1.2.~~

~~8.1. The provisions of this item will include the import of samples of raw materials, active ingredients forming part of sanitizing formulations not authorized for human consumption and in the technical analysis phase for registration with ANVISA, intended exclusively for carrying out control tests. of quality in an analytical laboratory installed in the national territory.~~

~~8.2. Products intended for market research will be excluded from this item, which will be submitted for an opinion from the competent technical area of ANVISA, at its headquarters, prior to its clearance.~~

~~8.3. The import of products referred to in this Section will take place through Siscomex or Remessa Expressa.~~

~~8.4. The import of the product will be exempt from shipping authorization~~ not external.

~~9. Commercialization and change of purpose informed in the procedure for import referred to in this Section.~~

~~SECTION IV~~

~~COSMETICS, PERFUMES AND PERSONAL HYGIENE PRODUCTS~~

~~10. The provisions of this Section cover the import of product samples in the form of finished products or in bulk, belonging to the class of cosmetics, perfumes and personal hygiene products, not regularized with ANVISA, and which are not expressly prohibited in the national territory , intended for laboratory analysis of quality control and evaluation of packaging and labeling, analysis for registration purposes, development of new products and market research, safety and efficacy trials.~~

~~10.1 The import referred to in the previous item must be subject to inspection by the health authority in office at the place of clearance of the good or product, upon presentation of a Petition for Inspection and Sanitary Release provided for in Chapter II, subitem 1.2, instructed by Term of specific Responsibility contained in Chapter XXII of these Regulations.~~

~~10.2. The import of products referred to in this Section will take place through SISCOMEX or Remessa Expressa.~~

~~10.3. The import of the product will be exempt from shipping authorization~~ not external.

10.4. The Term of Responsibility referred to in this Section must be presented with notarized signature.

11. Importation will be permitted by the laboratory authorized by the Brazilian Network of Health Analytical Laboratories - REBLAS, upon presentation of a declaration of authorization from the legal entity interested in carrying out the tests and a Petition for Inspection and Sanitary Release provided for in Chapter II, subitem 1.2 , instructed by the Term of Responsibility contained in Chapter XXII of these Regulations.

11.1. The importer referred to in the previous item will be released from the operating authorization for the import activity.

12. Commercialization and alteration of the purpose informed in the procedure for import referred to in this Section.

SECTION V

FOOD

13. The import of samples of raw materials and finished products, belonging to the food class, intended for analysis for registration purposes, quality control testing, packaging or labeling evaluation, development of new products or equipment participating in the process factory or laboratory and market research, must submit to inspection by the health authority in office at the place of clearance of the product, by presenting a Petition for Sanitary Inspection and Release provided for in Chapter II, subitem 1.2, instructed by a Term of Responsibility contained in of Chapter XXII of these Regulations.

13.1. Exceptions to the provisions of this item will be the import of food samples intended for analysis for registration purposes, quality control testing and equipment participating in the manufacturing or laboratory process, and market research that do not have:

a) substance or mixture of similar substances regulated before the National Health Surveillance System;

b) Identity and Quality Standard - PIQ - approved in Specific Technical Regulation.

13.2. The import referred to in the previous subitem must be analyzed and authorized by the competent technical sector at ANVISA headquarters prior to the fiscal action, to be carried out by the health authority in office at the place of clearance, through the presentation of a Petition for Inspection and Sanitary Release provided for. in Chapter II, subitem 1.2, instructed by the Term of Responsibility contained in Chapter XXII of these Regulations.

13.3. The requirement referred to in subitem 12.1 will not depend on whether or not product registration is mandatory.

13.4. The import of the product referred to in this Section will take place through the import modalities SISCOMEX or Express Shipping.

13.5. The import of the product will be exempt from shipping authorization not external.

13.6. The Term of Responsibility referred to in this Section must be presented with notarized signature.

13.7. The import of food samples with mandatory registration with ANVISA, the purpose of which is market research.

14. Commercialization and alteration of the purpose informed in the procedure for import referred to in this Section.

SECTION VI

FINAL PROVISIONS

15. The Petition for Sanitary Inspection and Release referred to in items 1, 5, 7 and 12 must be supported by a document presented with signature recognition at a notary's office, the technical responsible and legal responsible of the importing company, which must contain the following information:

a) purpose of import;

b) total quantity, justified, for the number of imported samples;

c) details of the qualitative and quantitative formula of the imported sample, except when dealing with medical products;

d) technical specifications of the imported sample;

e) batch numbers, or batches, and number of units produced per batch;

f) expiration date per batch of imported samples;

g) description of the tests to be carried out in the national territory, with a summary of the protocol justifying the quantity requested, when applicable;

h) description of the research methodology, if applicable;

i) occurrence of waste resulting from the operationalization of the purpose of proposed import, appropriate inactivation treatment methodology;

j) words on the product label, when dealing with food;

~~l) name of the technical person responsible for the imported product and respective information regarding the Individual Registration and Professional Council of their registration, identifying the registration number.~~

~~15.1. At the discretion of the health authority, for the purposes of the provisions of paragraph "j" of the previous item, the presentation of the respective translation into the national language of the label of the imported product, signed by the technical responsible and the responsible or legal representative of the importing company, may be requested. of the product with the National Health Surveillance System.~~

~~15.2. In the case of samples belonging to the class of medicines, in addition to the other requirements set out in this item, the importer will be obliged to present to the health authority in office at the place of clearance, after the product arrives in the national territory, the analytical report of control of the quality for each batch of imported sample and the Term of Responsibility contained in Chapter XXII.~~

~~15.3. The Term of Responsibility referred to in the previous sub-item must be presented with signature recognition at the notary's office of its subscribers, technical manager and legal representative of the importing company.~~

~~16. The Petition for Inspection and Sanitary Release of imported samples referred to in items 1, 5, 7, 9, and 12 must be filed with the sanitary authority in office at the place where the clearance will take place.~~

CHAPTER XXI

PRODUCT NOT REGULARIZED IN THE NATIONAL HEALTH SURVEILLANCE SYSTEM - SNVS - FOR REGISTRATION PURPOSES, INTENDED FOR MARKET RESEARCH, ANALYSIS LABORATORY, QUALITY CONTROL TESTS, PACKAGING EVALUATION OR EQUIPMENT LABELING AND TESTING

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

SECTION I

OF MEDICINES

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

1. The import of samples of finished products, in bulk or raw material, belonging to the class of medicines not regulated by ANVISA, intended for testing, must be subject to analysis and approval of the Import Licensing by the health authority, upon presentation of Petition for Health Inspection and Release, instructed by the Term of Responsibility contained in Chapter XXII of this Resolution.
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

2. The import of samples of non-regularized medicines must meet the sanitary requirements set out in procedures 1, 1A, 2, 2A, 2B, 2C, 3, 5.3 and 6, as applicable, of Chapter XXXIX of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.1. Documents relating to the regularization of the medicine before ANVISA, provided for in the procedures of Chapter XXXIX of this Resolution, are excluded from the provisions of item 2 of this Section. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.2. Also exempt from the provisions of item 2 of this Section is the requirement to present the Analytical Quality Control Report, per batch or batch, issued by the manufacturer when it is a finished product for the purpose of carrying out analytical tests that do not involve administration in human beings.
(Included by Resolution – RDC nº 599, of February 9, 2022)

3. The import referred to in this Section must be in a quantity compatible with the stated purpose. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

4. The import of medicines not regulated by ANVISA, intended for market research, is prohibited. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION II

MEDICAL PRODUCTS AND IN VITRO DIAGNOSTIC PRODUCTS

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

5. The import of samples of finished products belonging to the class of health products not regularized by ANVISA, intended for testing, teaching or training, must be subject to analysis and approval of the Import Licensing by the health authority, upon presentation of a Petition for Sanitary Inspection and Release, instructed by the Term of Responsibility contained in Chapter XXII of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

5.1. The import of the product will be exempt from shipping authorization abroad. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

6. The commercialization of product samples referred to in this Section is prohibited, as well as changing the purpose for which they are intended, informed in the import procedure. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION III

OF SANITIZERS

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

7. The import of product samples, in the form of finished products belonging to the class of household sanitizers, not regularized with ANVISA, and which are not expressly prohibited in the national territory, intended for analysis for registration purposes, quality control testing , proficiency, development of new products or equipment participating in the manufacturing or laboratory process, will occur through the presentation of a Petition for Sanitary Inspection and Release, provided for in Chapter II, subitem 1.2, instructed by the Term of Responsibility contained in Chapter XXII of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

7.1. The provisions of item 7 of this Section include the import of samples of raw materials, active ingredients forming part of sanitizing formulations not authorized for human consumption and in the technical analysis phase for registration before ANVISA, intended exclusively for carrying out quality control tests in an analytical laboratory installed in the national territory. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

7.2. Products intended for market research are excluded from the provisions of item 7 of this Section, which will be submitted for an opinion from the competent technical area of ANVISA at its headquarters, prior to its clearance. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

7.3. The import of the products referred to in this Section will take place through Siscomex or Express Shipping. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

7.4. The import of the product referred to in this Section will be exempt from authorization for shipment abroad. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

8. The commercialization of product samples referred to in this Section is prohibited, as well as changing the purpose for which the import is intended, as informed in the import procedure. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

SECTION IV

COSMETICS, PERFUMES AND PERSONAL HYGIENE PRODUCTS

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

9. The provisions of this Section cover the import of product samples, in the form of finished products or in bulk, belonging to the class of cosmetics, perfumes and personal hygiene products, not regularized with ANVISA, and which are not expressly prohibited in the territory national, intended for laboratory analysis of quality control and evaluation of packaging and labeling; analysis for recording purposes; new product development and market research; or safety and efficacy trials. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

9.1 The import referred to in item 9 of this Section must be subject to inspection by the health authority, upon presentation of a Petition for Sanitary Inspection and Release, provided for in Chapter II, subitem 1.2, which must be accompanied by a Term of Responsibility, contained in Chapter XXII of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

9.2. The import of the products referred to in this Section will take place through SISCOMEX or Express Shipping. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

9.3. The import of products referred to in this Section will be exempt from authorization for shipment abroad. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

10. The import referred to in this Section will be provided to a laboratory authorized by the Brazilian Network of Health Analytical Laboratories (REBLAS), upon presentation of a declaration of authorization from the legal entity interested in carrying out the tests and a Petition for Inspection and Sanitary Release, provided for in Chapter II, subitem 1.2, which must be instructed by a Term of Responsibility, contained in Chapter XXII, of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

10.1. The importer referred to in item 10 of this Section will be released from the operating authorization for importing activities. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

11. The commercialization of product samples referred to in this Section is prohibited, as well as changing the purpose for which the import is intended, as informed in the import procedure. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION V

FOOD

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

12. The import of samples of raw materials and finished products, belonging to the food class, intended for analysis for registration purposes, quality control testing, packaging or labeling evaluation, development of new products or equipment participating in the process factory or laboratory, or market research, must be subject to inspection by the health authority, through the presentation of a Petition for Health Inspection and Release, provided for in Chapter II, subitem 1.2, which must be instructed by a Term of Responsibility, contained in the Chapter XXII of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

12.1. Imports intended for market research will depend on a favorable opinion granted by the competent technical sector of ANVISA at its headquarters. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

12.2. The requirement referred to in sub-item 12.1 of this Section will not depend on the mandatory registration of the product. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

12.3. The import of products referred to in this Section will take place through the SISCOMEX or Express Shipping import modalities. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

12.4. The import of products referred to in this Section will be exempt from authorization for shipment abroad. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

12.5. The import of food samples with mandatory registration with ANVISA, the purpose of which is market research, will not be authorized.
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

13. The commercialization of product samples referred to in this Section is prohibited, as well as changing the purpose for which the import is intended, as informed in the import procedure. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION VI

FINAL PROVISIONS

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

14. The Petition for Sanitary Inspection and Release referred to in Sections I, II, III and IV of this Chapter must be supported by a document signed by the technical responsible and legal responsible of the importing Company, which must contain the following information: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) purpose of import; **(Wording given by Resolution – RDC nº 208, of 5 January 2018)**

b) total quantity, justified, for the number of imported samples; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) details of the qualitative and quantitative formula of the imported sample, except when dealing with medical products; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

d) technical specifications of the imported sample; **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

e) batch numbers, or batches, and number of units produced per batch; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

f) description of the tests to be carried out in the national territory, with a summary of the protocol justifying the quantity requested, when applicable; **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

g) description of the research methodology, if applicable; **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

h) occurrence of waste resulting from the operationalization of the proposed import purpose, appropriate treatment methodology and inactivation; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

i) name of the person technically responsible for the imported product and respective information regarding the Individual Registration and Professional Council of their registration, identifying the registration number. **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XXII

STATEMENT OF RESPONSIBILITY

The legal entity _____, CNPJ_____ duly regularized before the National Health Surveillance Agency, declares that the product(s) listed below will be imported without commercial or industrial purposes and are intended for- if, exclusively, the ___(identify purpose)_____

Item	Business Name	Group or category to which you belong	Lot number or match	Amount
01				
02				

I certify that the aforementioned product(s) comply with the legal provisions related to good manufacturing practices and finished product control, as well as the ingredients of its formulation are part of the lists of raw materials authorized in legislation relevant health care.

The undersigned assume health responsibility for damage to individual or collective health and the environment resulting from the change in the purpose of the product entering the national territory.

_____

TECHNICAL MANAGER LEGAL REPRESENTATIVE

CR No.

Note. The legal entity "Laboratory" is exempt from regularization with ANVISA.

CHAPTER XXIII

IMPORT OF HUMAN CELLS AND TISSUE FOR THERAPEUTIC PURPOSES

SECTION I

GENERAL PROVISIONS

1. The entry into the national territory of cells and tissues will only be authorized upon proof of their therapeutic purpose by the importer, and

criteria of the relevant legislation, including biosafety, meeting the sanitary requirements of this Regulation.

2. The import referred to in this Chapter, unless expressly provided, will take place through the import modalities in the Integrated Foreign Trade System - SISCOMEX - Import Module, Express Shipping, or Simplified Import Declaration, non-electronic, or Accompanied Baggage.

2.1. For import authorization purposes, the interested party must present the import request to the General Management of Blood, Other Tissues, Cells and Organs - GGSTO, accompanied by the information required in this Chapter at least 5 (five) business days before the expected date of arrival of the material in the national territory.

2.2. For the purposes of inspection and sanitary release, the importer must submit a Petition for Sanitary Inspection and Release to ANVISA, referred to in subitem 1.2. of Chapter II.

2.3 The import of cells, germinal tissues and human embryos from donors and the patient himself is prohibited, through the Accompanied Baggage and Unaccompanied Baggage modality. **(Included by Resolution – RDC nº 771, of December 26, 2022)**

3. The approval and sanitary release of the import of the material referred to in this Chapter, in the modalities described, will take place through the express manifestation of the sanitary authority in office at the place of clearance after satisfactory physical inspection, as well as an express and favorable manifestation import by the General Coordination of the National Transplant System - CGSNT, and a favorable technical opinion from the General Management of Blood, other Tissues, Cells and Organs - GGSTO - of ANVISA, at its headquarters, within the scope of its competences, issued upon receipt and evaluation of the requirements contained in this Chapter in document analysis.

~~3.1. The import of germinal cells and tissues and human pre-embryos will be exempt from the provisions of this item, which will only depend on the favorable technical opinion of the General Management of Blood, other Tissues, Cells and Organs - GGSTO.~~

3.1. The import of germ cells, germinal tissues and human embryos from donors and the patient himself will be exempt from the provisions of this item. **(Wording given Resolution – RDC nº 771, of December 26, 2022)**

3.2. The importer will be authorized to keep and be responsible for cells and tissues included in Sections III and IV of this Chapter, in environments appropriate to maintaining their integrity.

4. The importer is responsible for complying with regulatory and legal standards, measures, formalities and requirements for the administrative import process.

4.1. The provisions of this item will include the obligation to adopt appropriate measures, in person and with third parties contracted for the import of the material referred to in this Chapter, that avoid or prevent harm to health.

5. Omitted cases relating to the import of cells and tissues for therapeutic purposes will be examined jointly by the General Management of Ports, Airports, Borders and Customs Precincts - GGPAF, and by the General Management of Blood, other Tissues, Cells and Organs - GGSTO, and decided by the Director responsible for supervising this General Management of ANVISA.

6. The packaging, packaging and transport of biological material referred to in this Chapter must be carried out in such a way that its integrity is guaranteed and maintained, in an appropriate and exclusive container for the purpose of importation, at the appropriate temperature, and duly identified, in in accordance with the provisions of this Regulation and the relevant legislation, and, alternatively, the additional information indicated by the importer.

6.1. Packaging will be considered exclusively for the purposes of this Chapter.
external:

a) the rigid thermal container or resistant packaging for thermal insulation coating, when the biological material is transported with ice or dry ice or other refrigerating material used.

b) rigid packaging, used in transport containing "dry-shipper", when
the biological material is transported in liquid nitrogen.

7. The material referred to in this Chapter must be presented, upon arrival in the national territory, with external packaging identified in the native language or English language, with the following information:

a) name, full address, telephone number and identification of the importer, indicating the National Register of Individuals or National Register of Persons
Legal;

b) name, full address and telephone number of the institution of origin;

c) name, full address and telephone number of the destination health establishment, indicating the National Register of Legal Entities;

d) conservation conditions of the material with date and time of
conditioning;

e) weight of the container when leaving the supplier institution for material stored in dryshippers.

7.1. The identification referred to in this item must be easy to view in order to allow immediate reading, and must contain the requirements of biosafety standards.

7.2. The identification of musculoskeletal tissue, skin, heart valve and cornea covered by this item must contain the following words: "BIOLOGICAL MATERIAL FOR THERAPEUTIC PURPOSES".

7.3. The identification of germinal cells and tissues, embryos and hematopoietic progenitor cells referred to in this item must contain the following words: "BIOLOGICAL MATERIAL FOR THERAPEUTIC PURPOSES. SUBMISSION TO
IRRADIATION (X-RAYS)",

7.4. Packaging containing dry ice, liquid nitrogen or other cryogenic liquid must be marked externally, in accordance with national and international standards for the transport of dangerous products.

7.5. In the case of corneas, there must also be an expiration date.

8. The Health Surveillance Coordination of Ports, Airports and Borders in the States and Federal District must inform GGSTO of the storage and packaging conditions of biological material upon its arrival and additional observations related to its integrity.

SECTION II

IMPORTATION OF SKIN, MUSCULOSKELETAL TISSUE AND HEART VALVE

9. In addition to the provisions of Section I of this Chapter, the provisions of this Section and relevant legislation will apply to the import of skin, musculoskeletal tissue and heart valve.

10. The import of the material referred to in this Section must be subject to the express and favorable statement of the CGSNT through proof of import authorization, prior to its shipment abroad.

11. After an express and favorable statement from CGSNT, ANVISA will be responsible for inspection and sanitary release of the import of the material referred to in this Section.

11.1. The request for technical opinion referred to in item 3 of this Chapter must be instructed with the following information:

a) name and National Register of Individuals of the recipient;

b) type of biological material to be imported and quantity;

c) name and full address of the supplier institution that processed the material;

c) country of origin of the material to be imported;

d) country of origin of the material to be imported;

e) date of withdrawal, expiration date, storage and packaging conditions, type of processing and additional recommendations related to its quality and integrity;

f) identification of the carrier, location and expected date of arrival;

g) full name and address of the healthcare establishment or professional transplanter for which the material is intended.

11.2. The following must be sent with the import request documents:

a) report with the diagnosis issued by the professional responsible for the therapeutic procedure, justifying the procedure and importation;

b) authorization from the recipient to carry out the therapeutic procedure, or authorization from the parents/legal guardian, when the recipient is legally incapable, signed and notarized;

c) results of donor serological tests for markers of communicable infections HIV-1 and 2, Syphilis, Hepatitis B, Hepatitis C, HTLV I/II, Chagas disease, Toxoplasmosis, Cytomegalovirus, and others that may be required by the relevant legislation, as well as other mandatory serological controls in the country of origin;

d) results of microbiological tests, when applicable.

e) possible residues of chemical products used in the processing that may trigger adverse reactions.

f) information on the type of complementary sterilization.

12. Regarding packaging and transport:

a) the packaging must ensure the integrity and sterility of its contents and not pose a risk of releasing cytotoxic or pyrogenic substances into the product.

b) the material must be transported in a validated system for maintenance of appropriate temperature for each type of fabric, according to items 12.1, 12.2 and 12.3.

c) The thermal container must ensure the transit of the material at an appropriate temperature for a period of 24 (twenty-four) hours beyond the estimated time for the material to arrive at the destination location.

12.1. When dealing with bone pieces, the material must be packaged and packaged in:

a) triple, sterile plastic packaging, or primary packaging made of sterile glass and secondary packaging made of sterile plastic, or single packaging, made of sealed sterile glass, suitable for storing the tissues until use;

b) thermal container that guarantees the maintenance of a temperature below 6° C positive.

12.1.1. Except as provided for in subitem 12.1.b, the transport of freeze-dried bone is carried out at room temperature.

12.2. When dealing with soft tissues and skin, they must be packaged and packaged in:

a) double, sterile plastic packaging or primary sterile glass packaging, with secondary sterile plastic packaging suitable for storing the tissues until use;

b) thermal container that guarantees the maintenance of a temperature between 2 and 8° C positive;

12.3. When dealing with heart valves, the material must be packaged and packaged in:

a) plastic, double, sterile packaging suitable for storing the fabrics until use;

b) special tank for transportation containing liquid nitrogen, "dryshipper", to maintain a temperature of minus 150º C for 48 (forty-eight) hours beyond the estimated time for the material to arrive at the destination;

c) rigid external packaging to protect the dryshipper.

12.4. Between primary and secondary, or secondary and tertiary packaging, there is a label containing the following information:

a) name, full address and contact telephone number of the supplying institution;

b) identification of the donor;

c) unique alpha-numeric code identifying the tissue unit;

d) type of fabric;

e) when dealing with muscle-skeletal tissue and skin, specify the processing, the amount of tissue expressed in volume, weight, dimension or the combination of these measurement units when applicable;

f) expiration date;

g) storage conditions;

h) information that the product is authorized for use in humans;

i) possible residues of chemical products used in the processing that may trigger adverse reactions;

j) information on the type of complementary sterilization.

SECTION III

THE IMPORT OF HEMATOPOETIC PROGENITOR CELLS

13. In addition to the provisions of Section I of this Chapter, the provisions of this Section and in the relevant legislation.

14. The import referred to in this Section will take place through the CGSNT.

15. ANVISA will be responsible for monitoring and sanitary clearance of the import of the material referred to in this Section.

16. The technical opinion referred to in item 3 of this Chapter must be accompanied by a request for import with the following information:

16.1. Regarding data related to the recipient of the material:

a) name, National Health Card number and Brazilian Registry number of Bone Marrow Receptors (REREME);

b) medical report justifying the need for the procedure;

c) authorization from the recipient to carry out the therapeutic procedure, or authorization from the parents/legal guardian, when the recipient is legally incapable, signed and notarized.

16.2. Regarding data related to imported material:

a) name and full address of the institution providing the material;

b) results of donor serological tests for markers of transmissible infections HIV-1 and 2, Syphilis, Hepatitis B, Hepatitis C, HTLV I/II, Cytomegalovirus and others that may be required by the relevant legislation, as well as other controls mandatory serological tests in the country of origin. In the event of importing hematopoietic progenitor cells from umbilical cord and placental blood, the results of the mother's serological tests, and/or the results of the tests carried out in the umbilical cord and placental blood unit collected, must be informed, as provided for in relevant legislation. ;

b.1) the competent Health Authority of the receiving country must analyze the epidemiological profile of blood-transmissible pathologies existing in the country of origin of the material, and may require information or carry out other tests in the hematopoietic progenitor cell unit.

c) results of histocompatibility tests;

d) results of cell viability tests, total number of nucleated cells, number of granulocytic-monocytic colony-forming units
(CFU-GM), CD34 count , results of bacterial, aerobic and anaerobic, and fungal contamination tests, in accordance with the relevant legislation, when applicable;

e) collection date, storage and packaging conditions, and
complementary recommendations related to its quality and integrity;

f) country of origin of the material to be imported;

g) country of origin of the material to be imported;

h) identification of the carrier, location and expected date of arrival;

i) name and address of the transplant institution to which the material is intended.

17. The packaging, packaging and transportation of the material referred to in this Section must be carried out in such a way that the provisions of item 6 of this Chapter are observed.

17.1. When dealing with non-cryopreserved hematopoietic progenitor cells:

a) the material must be packed in a plastic bag, suitable for
blood components;

b) the material must be transported at a temperature between 4ºC and 24ºC, in a thermal container equipped with an internal temperature recording system that indicates values outside the established limits.

17.1.1. The time between the end of the collection and the beginning of the infusion must not exceed 48 (forty-eight) hours.

17.1.2. The material used to maintain the temperature of the container thermal material cannot be in direct contact with the primary packaging.

17.2. When dealing with cryopreserved hematopoietic progenitor cells at minus 135°C:

a) the material must be packed in a plastic bag, suitable for blood components;

b) the plastic bag must be stored at a temperature equal to or lower than minus 135ºC;

c) the material must be transported in a container:

c.1) kept in specific protective packaging;

c.2) suitable for dry transport, or "dry-shipper";

17.2.1 The volume of liquid nitrogen must be sufficient to maintain the temperature for a minimum period of 48 (forty-eight) hours beyond the estimated time for its arrival at the establishment that will carry out the infusion.

17.3. When dealing with hematopoietic progenitor cells cryopreserved at minus 80°C:

a) the material must be packed in a plastic bag, suitable for blood components;

b) the material must be transported in a system validated to maintain a temperature equal to or lower than minus 65ºC for a period of 24 (twenty-four) hours.

SECTION IV

THE IMPORT OF GERMINATIVE CELLS AND TISSUE AND PRE-EMBRYOS HUMANS

~~18. In addition to the provisions of Section I of this Chapter, the provisions of this Section and the relevant legislation will apply to the import of germinal cells and tissues and pre-embryos.~~

18. In addition to the provisions of Section I of this Chapter, the provisions of the relevant legislation and Collegiate Board Resolution (RDC) No. 771, of December 26, 2022, will apply to the import of germ cells, germinal tissues and human embryos. , its updates or whatever replaces it. **(Wording given Resolution – RDC nº 771, of December 26, 2022)**

~~19. The request for import must be sent to the General Management of Blood, other Tissues, Cells and Organs - GGSTO/ANVISA, with a document on the letterhead of the health establishment where the procedure will be carried out, and signed by the legal guardian and the professional responsible for the procedure.~~

(Revoked by Resolution – RDC nº 771, of December 26, 2022)

~~19.1 This document must contain the following information:~~ **(Revoked by Resolution – RDC nº 771, of December 26, 2022)**

~~a) identification of the destination health establishment (name and registration National Legal Entity), with identification of your health license;~~ **(Repealed by Resolution – RDC nº 771, of December 26, 2022)**

~~b) identification of the biological material, also describing its quantity;~~

(Revoked by Resolution – RDC nº 771, of December 26, 2022)

~~c) identification of the recipient, the receiving couple, or the owner of the material, with name, General Registry and National Register of Individuals;~~ **(Repealed by Resolution – RDC nº 771, of December 26, 2022)**

~~d) justification for the import;~~ **(Revoked by Resolution – RDC nº 771, of 26 December 2022)**

~~e) storage and packaging conditions, and additional recommendations related to their integrity and quality, until the moment of use;~~ **(Revoked by Resolution – RDC nº 771, of December 26, 2022)**

~~f) country of origin of the material to be imported;~~ **(Revoked by Resolution – RDC nº 771, of December 26, 2022)**

~~g) country of origin of the material to be imported;~~ **(Repealed by Resolution – RDC nº 771, of December 26, 2022)**

~~h) identification of the Bank of Germinal Cells and Tissues - BCTG in which the material will be stored, in case the importing health establishment, where the therapeutic procedure will be carried out, is not a BCTG.~~ **(Revoked by Resolution – RDC nº 771, of December 26, 2022)**

~~i) identification of the carrier, location and expected date of arrival.~~

(Revoked by Resolution – RDC nº 771, of December 26, 2022)

~~19.1.1. For the import of semen, ovarian and testicular tissues, in addition to the information in subitem 19.1, also provide the identification and full address of the supplying institution that processed the material to be imported;~~ **(Revoked by Resolution – RDC nº 771, of December 26, 2022)**

~~19.1.2. For the import of embryos, in addition to the information in subitem 19.1, also inform:~~ **~~(Revoked by Resolution~~ – RDC nº 771, of December 26, 2022)**

~~a) identification and full address of the supplier institution that performed the in vitro fertilization and that is storing the embryos;~~ **~~(Repealed by Resolution~~ – RDC nº 771, of December 26, 2022)**

~~b) date of the in vitro fertilization procedure and cryopreservation.~~ **(Revoked by Resolution – RDC nº 771, of December 26, 2022)**

~~19.2. The request for import must be accompanied by the following documents:~~ **~~(R~~evoked by Resolution – RDC nº 771, of December 26, 2022)**

~~a) copy of the health license of the health establishment where the procedure will be carried out;~~ **~~(Revoked by Res~~olution – RDC nº 771, of December 26, 2022)**

~~b) legible copy of identity documents and National Personnel Registry Physics of the recipient, receiving couple or the owner of the material;~~ **~~(Repealed~~ by Resolution – RDC nº 771, of December 26, 2022)**

~~c) diagnostic report issued by the professional responsible for the therapeutic procedure, justifying the procedure and importation;~~ **~~(Repealed~~ by Resolution – RDC nº 771, of December 26, 2022)**

~~d) written authorization from the recipient, the receiving couple or the owner of the material, to carry out the assisted reproduction procedure and to transport the material, signed and notarized, including the registration numbers General Registry and National Register of Individuals;~~ **~~(Repealed by R~~esolution – RDC nº 771, of December 26, 2022)**

~~e) copy of the health license of the BCTG in which the material will be stored, if the importing health establishment, where the therapeutic procedure will be carried out, is not a BCTG;~~ **~~(Revoked by Resolution – RDC nº 771, of December 26, 2022~~)**

~~19.2.1 To import embryos, in addition to the documents in 19.2, send a document from the institution of origin, which proves that the imported embryos belong to the couple.~~ **~~(Revoked by Resolution – RDC nº 771, of Dec~~ember 26, 2022)**

~~19.2.2. To import semen, ovarian and testicular tissues, in addition to the documents in 19.2, send a document from the institution of origin containing the results of the clinical, serological, microbiological and genetic tests carried out, to assess the risk of disease transmission.~~ **~~(Revoked by Resolution – RDC nº 771, of December 26, 2022)~~**

~~19.2.3. To import donated semen for therapeutic use by third parties, in addition to the documents in 19.2 and 19.2.2., send:~~ **~~(Revoked by Resolution – RDC nº 771, of December 26, 2022)~~**

~~a) document from the supplying institution, containing the phenotypic data of the donor;~~ **~~(Revoked by Resolution – RDC nº 771, of December 26, 2022)~~**

~~b) document proving the absence of available germ cells or tissues, issued by reputable legal entities from at least 3 (three) Germ Cell and Tissue Banks installed in the country.~~ **~~(Revoked by Resolution – RDC nº 771, of December 26, 2022)~~**

20. Regarding packaging and transport:

20.1. For transport, the internal temperature of the container containing the packaging must be adequate to maintain the integrity and quality of the imported material.

20.2. Wrapping, packaging and transportation must guarantee the safety of the material, including the amount of nitrogen in the container, which must be sufficient for a period of at least 48 (forty-eight) hours beyond the period foreseen for customs clearance.

20.3. The person responsible for packaging the material abroad must issue a declaration, which will accompany the container with the biological material, containing the following information:

a) full name and address of the institution supplying the imported material;

b) date and time of packaging;

c) weight of the container when leaving the supplying institution;

d) name, full address and telephone number of the destination health establishment, indicating the National Register of Legal Entities.

SECTION V

IMPORTATION OF HUMAN CORNEAS

21. In addition to the provisions of Section I of this Chapter, the provisions of this Section and the relevant legislation will apply to the import of human corneas for transplant purposes.

22. The import of the material referred to in this Section must be subject to express and favorable statement from the SNT.

23. The import referred to in this Section will take place by the patient registered on the transplant waiting list.

23.1. The patient registered on the transplant waiting list may grant powers to a third party to carry out the import referred to in this Section, as long as they prove this condition of the grantee.

24. ANVISA will be responsible for monitoring and sanitary clearance of the import of the material referred to in this Section.

25. The technical opinion referred to in item 3 of this Chapter must be supported by the presentation of the document described in subitem 25.1 and request for import.

25.1. Document referring to the patient provided by the Organ Notification, Procurement and Distribution Center - CNCDO, of the patient's respective State of residence containing the following information:

a) name and National Health Card;

b) illness that indicates transplantation;

c) date of inclusion and patient number on the waiting list;

d) identification in the Professional Council of the technical person responsible for the team that will perform the transplant;

e) name and full address of the health establishment where the procedure will be carried out.

25.2. The import request must contain the following information:

a) name and full address of the institution of origin responsible for tissue removal, processing and release;

b) withdrawal and expiration date, preservation means used with the batch, storage and packaging conditions, and additional recommendations related to its quality and integrity;

c) country of origin of the material to be imported;

d) country of origin of the material to be imported;

e) identification of the carrier, location and date of arrival;

26. The results of the donor's serological tests for markers of communicable diseases: HIV-1 and

2, Hepatitis B, Hepatitis C and others that may be required in relevant health legislation.

27. Forms from the institution of origin with information about the donation, the donor (cause of death, age) and evaluation of the cornea must be sent together with the tissue.

28. The maximum tolerable shelf life for imported human corneas will be determined by the conservation solution, as specified by the manufacturer from the date of preservation, observing the environmental conditions required for their maintenance and conservation, and must arrive in the country by at least 7 (seven) days before the expiration date.

29. The packaging, packaging and transportation of the material referred to in this Section must be carried out in such a way that the provisions of item 6 of this Chapter are observed, and must also:

a) be packed in primary packaging identified with a label, which must be protected against mechanical shock;

b) be transported in a thermal container with a temperature between 2ºC and 8ºC, which must have an internal temperature recording monitoring system that detects values outside these limits.

29.1. The refrigerant material used to maintain the temperature of the thermal container cannot be in direct contact with the primary packaging.

29.2. The temperature must be maintained for carrying out internal transport, until arrival at the final destination.

30. The results of the post-transplant corneal evaluation must be sent to GGSTO, by the professional responsible for the procedure/transplant, six months after the procedure.

CHAPTER XXIV

HUMAN BIOLOGICAL MATERIAL FOR LABORATORY DIAGNOSTIC PURPOSES

1. The import of material of a human biological nature intended for laboratory diagnosis and of reference material originating from human biological material intended for the implementation of analytical methodology in an establishment providing a human clinical diagnosis service must be subject to prior clearance in the national territory , to the express and favorable statement of the competent health authority.

1.1. The provisions of this item will include material coming from abroad destined to:

a) clinical, biological, microbiological and immunological examinations linked to screening to verify compatibility between international donors and patients with a medical indication for transplant, in the national territory;

b) proficiency tests in laboratories belonging to the network of special public health programs.

c) proficiency tests in private laboratories linked to the development of international proficiency programs.

d) laboratory diagnosis linked to official Public Health programs.

1.2. The requirements of the relevant health legislation related to the packaging, transport and storage of biological material of human nature must be complied with.

2. The import of material of human biological nature referred to in this Chapter will take place through the SISCOMEX modalities - Import Module, Express Shipment or Postal Shipment, and the importer must request its inspection through a Petition for Inspection and Release Health provided for in Chapter II, subitem 1.2, and instructed by the Term of Responsibility included in Chapter XXV of these Regulations.

~~2.1. The Term of Responsibility must be presented with notarized signature.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~2.1.1. Signatories authorized by those responsible for the Management of the National System of Public Health Laboratories will be exempt from the requirement for signature recognition at a notary's office.~~ **~~(Revoked by Resolution – RDC nº 208, of~~ January 5, 2018)**

3. Material of human biological nature, imported through the SISCOMEX - LI will be exempt from the obligation to authorize boarding abroad.

4. Importation will be authorized by an individual, technically responsible for a healthcare establishment providing human clinical laboratory diagnosis services of reference or proficiency standards, originating from human biological material for the purposes of implementing and developing analytical methodology.

4.1. The natural person referred to in this item, in addition to complying with the other provisions of this Chapter, must attach to the Petition referred to in item 2, a document proving their relationship and professional role with the health establishment, where the methodology will be implemented or developed. .

4.2. The document referred to in the previous subitem must be presented at the its original form, and:

a) be signed by the legal representative of the health establishment with notarized signature;

b) express the commitment to observe and comply with the standards and procedures established by health legislation, as well as being aware of the penalties to which it will be subject, under the terms of Law No. 6,437, of August 20, 1977.

5. In exceptional situations, in geographical border areas, the importation by an individual of human biological samples intended for clinical laboratory diagnosis may be authorized, upon presentation to the competent health authority in office, of a medical prescription indicating the type examination to be carried out.

6. Human biological samples must be presented properly packaged and in appropriate packaging provided for in current legislation.

CAPITULO XXV

RESPONSIBILITY TERM FOR IMPORTATION OF BIOLOGICAL MATERIAL HUMAN FOR LABORATORY DIAGNOSTIC PURPOSES

The Company _____, declares that the material(s):

Item	Identification of biological material under import	No. of units	Specification of the type(s) of analysis(ies)
01			
02			

It was imported not for use in humans and intended exclusively for the purpose of:

	Laboratory diagnosis for commercial purposes
	Laboratory diagnosis for non-commercial purposes
	Clinical laboratory diagnosis linked to clinical research in the national territory
	Clinical laboratory diagnosis linked to clinical research abroad

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

	Clinical laboratory diagnosis linked to transplant screening
	Laboratory diagnosis linked to Official Public Health Programs
	Proficiency or development/installation/diagnosis of methodology for laboratory diagnosis;

Additional Information:

a) title of the research when it is clinical research or scientific research, when applicable;

b) CE number or copy of the document and identification of the competent official body that regularized the research, when applicable;

c) full name and address and country of the sending institution;

d) country of origin of the material that integrates the imported material;

e) country of origin of the imported material;

f) complete address of the importer;

g) name and full address of the recipient institution,

h) name and full address of the place where the laboratory diagnosis will be carried out;

i) name and respective registration with the class council of the researcher at the institution responsible for the research;

j) valid health license or corresponding document, issued by the competent authority of the State, Municipality or Federal District, where the analytical laboratory is located, when it is a mandatory requirement contained in relevant legislation of the UF;

l) visual identification of imported material.

The undersigned assume health responsibility for damage to individual or collective health and the environment resulting from the change in the purpose of the product entering the national territory.

_____

TECHNICAL MANAGER LEGAL REPRESENTATIVE

CR No.

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XXVI

CLINICAL RESEARCH

SECTION I

OF THE PRODUCT OBJECT OF THE CLINICAL RESEARCH

1 - The import for clinical research purposes of goods or products belonging to the classes of medicines (including products intended for dietary interventions that do not form part of the class of foods subject to registration), medical products or products for in vitro diagnosis must be subject to authorization to board abroad in Import Licensing, with SISCOMEX, upon presentation of an appropriate form provided for in relevant legislation. **(Revoked by Resolution - RDC nº 9, of February 20, 2015)**

(Revoked by Resolution - RDC nº 10, of February 20, 2015)

1.1. The initial request for Import Licensing (LI) shipping authorization must be filed with ANVISA, at its headquarters, and must comply with other current health regulations. For subsequent shipment authorizations, LI approval will occur at the place where the products are cleared;

These assessments will be based on and supported by the initial boarding authorization granted by the competent technical area, as provided for in relevant legislation.
(Revoked by Resolution - RDC nº 9, of February 20, 2015) (Revoked by Resolution - RDC nº 10, of February 20, 2015)

1.2. The approval of Import Licensing and the sanitary release of goods or products will be given by the competent sanitary authority in office in the
place of clearance of the product, by complying with the provisions of this Regulation, as well as compliance with the labeling and packaging, transport and storage instructions, in accordance with the product regulations before ANVISA, or, alternatively, those provided by the manufacturer.

1.2.1 For imported medicines produced by a manufacturer other than the importer or sponsor of the clinical study, the certificate of analysis for the finished product may be replaced by:

a) copy of the medicine purchase invoice, specifying all batches;

b) declaration, containing batch number, name of the active ingredient and commercial name of the medicines as they are sold on the foreign market, signed by the technical responsible.

1.2.2. In addition to the provisions of the previous subitem, they must be presented, after the arrival of the product in the national territory, the following documents:

a) copy of the Special Notice - CE, issued by the competent technical area of the ANVISA at its headquarters;

b) bill of lading - AWB, BL or CTR;

c) authorization of access for inspection, in accordance with the relevant tax regulations, when applicable;

d) commercial invoice.

SECTION II

IMPORTED MEDICAL PRODUCTS AND IN VITRO DIAGNOSTIC PRODUCTS FOR FOLLOW-UP OR EVALUATION OF CLINICAL RESEARCH

2. The import of goods and products under health surveillance belonging to the classes of medical products and in vitro diagnostic products linked to the monitoring and evaluation of the development of approved clinical research must be subject to authorization for shipment under import licensing - LI by the area competent technician of ANVISA at its headquarters, upon presentation of the appropriate form provided for in relevant legislation. **(Repealed by Resolution RDC nº 10, of February 20, 2015)**

2.1. The initial request for Import Licensing - LI shipment authorization must be filed with ANVISA, at its headquarters, and must comply with other current health regulations. **(Revoked by Resolution - RDC nº 10, of February 20, 2015)**

2.1.1. For subsequent shipment authorizations, approval of the LI will occur at the place of clearance of the products, and will be based and supported by the initial shipment authorization granted by the competent technical area, as provided for in relevant legislation. **(Revoked by Resolution - RDC nº 10, of February 20, 2015)**

2.2. The approval of the Import Licensing, with SISCOMEX, will take place through the presentation of a Petition for Inspection and Sanitary Release provided for in Chapter II, subitem 1.2 before the sanitary authority in office at the place of clearance and compliance with the labeling instructions and packaging, transport and storage, in accordance with the product regulations before ANVISA, or, alternatively, those provided by the manufacturer.

SECTION III

KITS FOR COLLECTION OF BIOLOGICAL MATERIAL LINKED TO THE CLINICAL RESEARCH FOLLOW-UP OR EVALUATION

3. The import of kits for the collection of biological material, linked to the monitoring and evaluation of the development of approved clinical research, must be subject to inspection by the competent health authority in office at the place of clearance, upon presentation of a Petition for Inspection and Health Release provided for in Chapter II, subitem 1.2, instructed by the Term of Responsibility contained in Chapter XXVII, of these Regulations, presented with notarized signature and accompanied by the following documents:

a) bill of lading - AWB, BL or CTR;

b) authorization of access for inspection, in accordance with the relevant tax regulations, when applicable;

c) commercial invoice.

d) copy of the Special Notice - CE, issued by the competent technical area of the ANVISA at its headquarters;

3.1. The import referred to in this Section will take place through SISCOMEX Express Shipping or Postal Shipping and will be exempt from shipping authorization abroad.

4. Commercialization and alteration of the purpose informed in the procedure for import referred to in this Section.

5. The approval of the Import Licensing and the sanitary release of goods or products will be carried out by the competent sanitary authority in office at the place of clearance upon compliance with the provisions of this Regulation, as well as compliance with the labeling and packaging instructions, transport and storage, in accordance with the product regulations before ANVISA, or, alternatively, those provided by the manufacturer.

6. The goods or products referred to in this Section will be exempt from regularization before ANVISA.

SECTION IV

OF HUMAN BIOLOGICAL MATERIAL LINKED TO CLINICAL RESEARCH IN DEVELOPMENT ABROAD, INTENDED FOR LABORATORY DIAGNOSIS CLINICAL

7. The import of human biological material linked to the monitoring and evaluation of research development, intended for clinical laboratory diagnosis must be subject to inspection by the competent health authority in exercise at the product clearance site, by presenting a Petition for Inspection and Sanitary Release provided for in Chapter II, subitem 1.2, instructed by the Term of Responsibility contained in Chapter XXVII, of these Regulations,

presented with notarized signature and accompanied by the following documents:

a) bill of lading - AWB, BL or CTR;

b) authorization of access for inspection, in accordance with the relevant tax regulations;

c) commercial invoice.

7.1. The import of goods and products referred to in this Section will take place through through SISCOMEX, Express Remittance or Postal Remittance.

7.2. The import of the good or product referred to in this Section will be exempt from authorization for shipment abroad.

8. Commercialization and alteration of the purpose informed in the procedure for import referred to in this Section.

9. The approval of the Import Licensing and/or sanitary release of the material will be given by the competent sanitary authority in office at the place of clearance upon compliance with the provisions of this Regulation, as well as compliance with the labeling and packaging instructions, transportation and storage, according to the information indicated by the exporter of the material.

SECTION V

FINAL PROVISIONS

10. The imports covered by this Chapter will be subject to physical inspection, at the discretion of the health authority.

11. The secondary and external packaging used for the movement and transport of the materials referred to in this Chapter must contain:

a) the number of the clinical protocol to which the good or product is subjected to clinical research referred to in Section I;

b) quantity of imported material;

c) information on special storage precautions, such as temperature, humidity, luminosity;

d) information on physical form or pharmaceutical form relating to the presentation of the product, referred to in Section I;

~~12. Materials not regulated by ANVISA will be prohibited from entering the national territory for clinical research purposes, without prior approval from the competent health authority.~~

CHAPTER XXVI

CLINICAL RESEARCH

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

SECTION I

OF THE PRODUCT OBJECT OF THE CLINICAL RESEARCH

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

1. The import of products belonging to the classes of medicines, medical products or in vitro diagnostic products under investigation, for exclusive use in clinical research, must be subject to analysis and approval of Import Licensing by the health authority, upon presentation of a Petition for Health Inspection and Release, with SISCOMEX. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

1.1 The importer must inform in the product description the number of the Special Communication (CE) or Specific Special Communication (CEE) or Document for Import of Product(s) under investigation in the Drug Clinical Development Dossier (DDCM) or Clinical Investigation Dossier of Medical Device (DICD), issued by the competent technical area of Anvisa at its headquarters. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

1.2. The following are mandatory documents for the instruction of the import process referred to in this Section: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Bill of lading cargo; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Commercial invoice; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) In cases of imports carried out by people other than the holder of the DDCM or DICD, a document delegating import responsibilities.
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

2. The entry into the national territory of products under investigation not provided for in the CE, CEE or Document for Import of Product under investigation in the Medicinal Clinical Development Dossier (DDCM) or Dossier of

Clinical Investigation of Medical Device (DICD). **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

3. Changing the purpose of importing the goods and products referred to in this Section is prohibited. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION II

IMPORTED MEDICAL PRODUCTS AND IN VITRO DIAGNOSTIC PRODUCTS FOR FOLLOW-UP OR EVALUATION OF CLINICAL RESEARCH

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

4. The import of goods and products under health surveillance belonging to the classes of medical products and in vitro diagnostic products, linked to the monitoring and evaluation of the development of approved clinical research, will take place through the presentation of a Petition for Inspection and Sanitary Release, provided for in Chapter II, subitem 1.2 and compliance with labeling, packaging, transport and storage instructions. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION III

KITS FOR COLLECTION OF BIOLOGICAL MATERIAL LINKED TO THE CLINICAL RESEARCH FOLLOW-UP OR EVALUATION

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

5. The import of kits for collecting biological material, linked to the monitoring and evaluation of the development of approved clinical research, must be subject to inspection by the health authority, upon presentation of a Petition for Inspection and Sanitary Release, provided for in Chapter II , subitem 1.2, which must be instructed by a Term of Responsibility, contained in Chapter XXVII of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

5.1 The importer must inform, in the product description, the number of the Special Communication (CE) or Specific Special Communication (CEE) or Document for Import of Product(s) under investigation in the Medicines Clinical Development Dossier (DDCM) or Dossier of Medical Device Clinical Investigation (DICD), issued by the competent technical area of Anvisa at its headquarters. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

5.2. The documents are mandatory for the instruction of the import process referred to in this Section: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Bill of lading cargo; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Commercial invoice; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) In cases of imports carried out by people other than the holder of the DDCM or DICD, a document delegating import responsibilities.
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

5.3. The import referred to in this Section will take place through SISCOMEX, Express Remittance or Postal Remittance and will be exempt from authorization for shipment abroad. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

6. The commercialization of the products referred to in this Section is prohibited, as well as changing the purpose for which the import is intended, as informed in the import procedure. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

7. The goods or products referred to in this Section are exempt from regularization before ANVISA. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION IV

OF HUMAN BIOLOGICAL MATERIAL LINKED TO CLINICAL RESEARCH IN DEVELOPMENT ABROAD, INTENDED FOR LABORATORY DIAGNOSIS CLINICAL

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

8. The import of human biological material, linked to the monitoring and evaluation of research development, intended for clinical laboratory diagnosis, must be subject to inspection by the health authority, through the presentation of a Petition for Health Inspection and Release, provided for in Chapter II , subitem 1.2, which must be instructed by a Term of Responsibility, contained in Chapter XXVII of this Resolution, accompanied by the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Declaration from the Importer with information on the Notice number Special (CE) or Specific Special Announcement (CEE); **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

b) Bill of lading cargo; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) Commercial invoice. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

8.1. The import of goods and products referred to in this Section will take place through SISCOMEX, Express Shipping or Postal Shipping. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

8.2. The import of goods or products referred to in this Section is exempt from authorization for shipment abroad. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

9. The commercialization of the products referred to in this Section is prohibited, as well as changing the purpose for which the import is intended, as informed in the import procedure. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

10. The approval of the Import Licensing or the sanitary release of the material will take place upon compliance with the provisions of this Resolution, as well as compliance with the indications for labeling and packaging, transport and storage, in accordance with the information indicated by the exporter of the material and regulated by national and international transport standards. **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

SECTION V

FINAL PROVISIONS

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

11. The imports covered by this Chapter will be subject to physical inspection, at the discretion of the health authority. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

12. The secondary and external packaging used for the movement and transportation of the materials referred to in this Chapter must contain: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Number of the clinical protocol of the research to which the product is submitted; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) information on storage precautions, such as temperature, humidity and light; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) batch number or identification code or serial number that allows traceability of the imported product. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

12.1 Medicines imported only in primary packaging and containing a QR Code or other identifier must meet the minimum requirements described in paragraphs a and b, in their external or transport packaging. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

12.2 The information linked to the QR Code or other identifier must allow complete traceability of the product with the research center. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

CHAPTER XXVII

DISCLAIMER FOR IMPORTS FOR RESEARCH CLINIC

The legal entity _____ declares that the product(s) listed below will be imported without commercial and industrial purposes and for the exclusive purpose of monitoring and/or evaluating approved clinical research.

Item	Type of material imported	Identification of the material(is) human to be collected	Notice No. Approved Research Special	No. of Units
01				
02				

The undersigned assume health responsibility for damage to individual or collective health and the environment resulting from the change in the purpose of the product entering the national territory.

_____

TECHNICAL MANAGER LEGAL REPRESENTATIVE

CR No.

~~CHAPTER XXVIII~~

~~SPECIAL CUSTOMS SITUATIONS~~

~~SECTION I~~

~~CUSTOMS TRANSIT~~

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

1. The import of goods and products under non-automatic licensing with SISCOMEX, subject to customs transit regime through the International Cargo Manifest and Customs Transit Clearance - MIC/DTA -, Customs Transit Clearance - DTA - and Customs Transit Clearance Simplified Customs Transit - DTA-S, are exempt from consent or authorization from ANVISA.

1.1. The import of perishable goods and products or those requiring special storage will be exempt from the provisions of this item, which must have authorization for customs transit granted by the health authority, at the place of entry into the national territory. **(Requirement suspended by Resolution - RDC nº 48, of August 31, 2012)**

1.2. Exceptions to the provisions of this item will be made for imports destined for the Customs Warehousing Regime, Free Store and for consumption on board land vehicles that operate international public transport of passengers, aircraft and foreign-flagged vessels in transit or under charter from a Brazilian company. .

1.3. The approval of Import Licensing or an appropriate customs document, and the sanitary release of products subject to the customs transit regime will be carried out by the competent sanitary authority in office in the place where customs clearance will take place.

2. The application of customs transit regime to the import of goods and products belonging to the following classes and categories will be prohibited:

a) substances and medicines subject to special control, contained in the Procedures 1 and 1-A, of Chapter XXXIX, of these Regulations;

b) human cells and tissues for therapeutic purposes;

c) bulk, semi-manufactured or finished medicines belonging to the categories of blood products and biologicals, and the raw materials that comprise them, contained in Procedures 2, 2-A, 2-B, 2-C and 5.3, of Chapter XXXIX , of this Regulation;

d) finished products belonging to the classes of medicines, foods and medical products, when intended for clinical research;

e) Thalidomide and medicines based on this active ingredient.

2.1. Exceptions to paragraphs "b" and "c" of this item will be made for imports intended for public health programs, linked to the Ministry of Health, and State and Municipal Secretariats.

2.2. The import of goods and products belonging to the class of medical products linked to the monitoring and evaluation of clinical research development will be excluded from the provisions of paragraph "d".

~~3. Customs transit of goods or products will be prohibited under suspicion of compromising the identity and quality standard, or in emergency and provisional situations due to measures related to the international sanitary and epidemiological context.~~

~~3.1. For the purposes of this item, at the discretion of the health authority or in compliance with an emergency and provisional measure, the good or material will be subject to inspection at the place of entry into the co~~untry.

~~**SECTION II**~~

TEMPORARY ADMISSION

~~4. The import of goods or products under health surveillance and subject to non-automatic licensing at SISCOMEX, under a Special Customs Regime for Temporary Admission, must comply with the application and processing formalities, in accordance with the provisions of Chapter XXXIX of this Regulation.~~

~~5. The importer must request shipping authorization from the health authority through a Petition for Inspection and Sanitary Release provided for in Chapter II, subitem 1.2, accompanied by the following information complementary to the other parts of this Regulation~~:

~~a) name of the person technically responsible for the good or product during the period of its stay in the national territor~~y;

~~b) quantity of the good or product;~~

~~c) expiration date or expiration date of the good or product, as applicable;~~

~~d) purpose of import;~~

~~e) period of permanence of the product in the national territory, indicating the date of its return abroad;~~

~~f) place of storage or display of the product within the period subject to Temporary Admission.~~

~~5.1. The importer must present the respective proof of export to the health authority in office at the customs clearance location, within a maximum period of 10 (ten) business days from the shipment of the goods abroad.~~

~~5.2. Remaining the good or product under the Temporary Admission Customs Regime for a period longer than that indicated in paragraph "e" of the previous subitem will subject the importer to applicable sanitary sanctions.~~

6. The approval of the Import License and the Sanitary Release will take place by the ANVISA health authority, at the customs clearance location.

7. In accordance with this Regulation, for the purposes of the Special Customs Regime of Temporary Admission, the importation of goods or products listed in Procedures 4 and 5 of Chapter XXXIX is authorized.

7.1. Food is excluded from this item.

8. The nationalization of goods or products admitted under the Regime will be prohibited. Special Customs for Temporary Admission that does not comply with health legislation.

SECTION III

CUSTOMS WAREHOUSE

9. The import of goods or products under sanitary surveillance under the Special Customs Warehouse Regime must be communicated by the importer or consignee to the sanitary authority in office at the place of customs clearance, within a period not exceeding 5 (five) working days from the date of permission. for this regime, by submitting a Petition for Inspection and Health Release provided for in Chapter II, subitem 1.2. and regularized regarding the Operating Authorization for this activity.

9.1. The communication must be accompanied by the document that authorizes the Special Customs Warehousing Regime, in its original form and a copy for authentication, which will be retained, and must contain the following information:

a) common name or technical, chemical or biological name of the good or product, when it is a raw material;

b) name of the food raw material, when it is food;

c) commercial name, when dealing with a finished or bulk product and a product belonging to the class of medicines, the name of the active ingredient based on the formulation must also be informed; for the food class, the product name and brand;

d) number or code of batches or production batches of goods or products stored;

e) expiration date per batch or batch;

f) information on the regularization of the product with ANVISA, if any;

g) identification of the company to which the regime was granted, indicating the National Register of Legal Entities and full address;

~~h) name of the manufacturer;~~

~~i) information on the regularization of the importing company with ANVISA, if any;~~

~~j) identification of the customs area or warehouse;~~

~~l) location of the good or product in the customs area;~~

~~m) special care for storage and maintenance of the identity and quality of the stored good or product, such as temperature, humidity, light, among others.~~

~~10. In case of return of goods and products referred to in this section, the importer must prove the shipment abroad to the health authority in office in the customs storage area of the product, within a maximum period of 5 (five) working days from the issuance of the customs document.~~

~~10.1. The proof that this item deals with must be carried out by the presentation of the aforementioned customs document with a copy, which will be retained.~~

~~11. The application of a Special Customs Warehousing Regime to import of goods and products belonging to the following classes and categories:~~

~~a) substances and medicines subject to special control, contained in the Procedures 1 and 1-A, of Chapter XXXIX, of these Regulations;~~

~~b) human cells and tissues for therapeutic purposes;~~

~~c) bulk, semi-manufactured or finished medicines belonging to the categories of blood products and biologicals, and the raw materials that comprise them, contained in Procedures 2, 2-A, 2-B, 2-C and 5.3, of Chapter XXXIX , of this Regulation;~~

~~d) finished products belonging to the classes of medicines, foods and medical products, when intended for clinical research;~~

~~e) thalidomide and medicines based on this active ingredient, raw materials and products forming part of Procedure 6 of Chapter XXXIX, of these Regulations.~~

~~11.1. Imports destined for public health programs, linked to the Ministry of Health and State and Municipal Secretariats, will be exempt from the provisions of paragraph "c" of this item.~~

~~11.2. The import of goods or products belonging to the classes of medical products linked to the monitoring and evaluation of clinical research development will be excluded from the provisions of paragraph "d".~~

12. The nationalization of the good or product imported under permission of the Special Customs Warehouse Regime must undergo sanitary inspection by the competent sanitary authority in office, in the place where its clearance will take place, in accordance with the criteria in Chapter XXXIX of this Regulation.

SECTION IV

FRACTIONAL DELIVERY

13. The import of goods or products under sanitary surveillance with fractional delivery, if the sanitary conditions are met, will be subject to the granting of Import Licensing with reservations from SISCOMEX by the sanitary authority in office at the place of customs clearance, upon arrival of the first imported fraction.

13.1. The fractional imports referred to in this item must be communicated to the health authority in office at the place of customs clearance of goods or products, at least 12 (twelve) hours in advance of the estimated date and time of their arrival.

13.2. Communication within a period shorter than that indicated in the previous subsection will subject the importer to applicable health sanctions.

13.3. The reservation referred to in this item must be recorded in the field referring to the Import Licensing situation at SISCOMEX with the following text: "PRODUCT UNDER FRACTIONAL DELIVERY. THE RELEASE FOR DISPLAY OR DELIVERY FOR CONSUMPTION OF THE FRACTIONAL SHIPMENTS INTEGRATED OF THIS IMPORT LICENSING SHALL BE GIVEN UPON SATISFACTORY INSPECTION BY THE HEALTH AUTHORITY IN OPERATION AT THE PLACE OF CLEARANCE".

14. The import referred to in this Section must be accompanied by a declaration from the importer taking responsibility for communicating the entry of each fraction of goods or products of the total indicated in the Import Licensing, signed by the company's legal representative, with notarized signature .

15. Release will only occur after health inspection by the authority in exercise at the customs clearance location, in accordance with this Regulation.

SECTION V

EARLY GRANTING OF IMPORT LICENSING

16. The advance approval of Import Licensing with the SISCOMEX may occur when importing perishable goods or products:

~~a) in case of failure to provide a storage environment with operational conditions compatible with the manufacturer's specifications for the purpose of maintaining safety and sanitary integrity;~~

~~b) in case of insufficient storage capacity.~~

~~c) in imports by public administration bodies and entities, direct and indirect, federal, state and municipal, including public companies and mixed-economy companies.~~

~~16.1. The Import Licensing referred to in this item will be granted with reservation by the health authority in office at the place of customs clearance.~~

~~16.2. The import referred to in this item must be communicated to the health authority in office at the place of customs clearance of the products, at least 24 (twenty four) hours in advance of the estimated time of arrival.~~

~~16.3. Communication within a period shorter than that indicated in the previous subsection will subject the importer to applicable health sanctions.~~

~~16.4. The exception referred to in subitem 16.1. must be registered in the field referring to the status of the Import Licensing in SISCOMEX with the following text: "EARLY APPRECIATION. THE RELEASE, DISPLAY OR DELIVERY FOR CONSUMPTION OF THE GOODS OR PRODUCTS COMPRISING THIS LICENSING IMPORTATION WILL BE SUBJECT TO INSPECTION BY THE HEALTH AUTHORITY IN EXERCISE AT THE PLACE OF CLEARANCE."~~

~~17. Sanitary release will only occur after physical inspection of the import, at the discretion of the sanitary authority, in office at the customs clearance location, in accordance with this Regulation.~~

~~17.1. In the case of exposure to consumption without release by the health authority, of products under advance approval, the importer will be held responsible and subject to the penalties of current legislation.~~

~~18. The importer may request an extension of the validity period of the Import Licensing for a period of 90 (ninety) days from the expiration of its validity period.~~

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XXVIII

SPECIAL CUSTOMS SITUATIONS

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

SECTION I

CUSTOMS TRANSIT

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

1. The customs transit regime through the International Cargo Manifest and Customs Transit Clearance (MIC/DTA), Customs Transit Clearance (DTA), International Waybill-Bill - Customs Transit Declaration (TIF-DTA), Transfer Transit Declaration (DTT) or Container Transit Declaration (DTC) is exempt from consent or authorization before ANVISA.
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

2. The application of a customs transit regime to the import of goods and products belonging to the following classes and categories is prohibited: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) substances and medicines subject to special control, contained in the Procedures 1 and 1A of Chapter XXXIX of this Resolution; **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

b) Thalidomide and medicines based on this active ingredient; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) human cells and tissues for therapeutic purposes; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

d) goods or products suspected of compromising the identity and quality standard, or in emergency and provisional situations, due to measures related to the international sanitary and epidemiological context. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.1. For the situation described in paragraph “d” of item 2 of this Section, at the discretion of the health authority, the good or material may, at any time, be subject to inspection. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION II

TEMPORARY ADMISSION

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

3. The import of goods or products under health surveillance and subject to non-automatic licensing at SISCOMEX, under a Special Customs Regime for Temporary Admission, must comply with the application and processing formalities, in accordance with the provisions of Chapter XXXIX of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

4. The importer must present the following additional information to the other parts of this Resolution: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) name of the person technically responsible for the good or product during the period of its stay in the national territory; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) quantity of the good or product; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) expiration date or expiration date of the good or product; **(Essay given by Resolution – RDC nº 208, of January 5, 2018)**

d) purpose of import; **(Wording given by Resolution – RDC nº 208, of 5 January 2018)**

e) period of permanence of the product in the national territory, indicating the date of its return abroad; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

f) place of storage or display of the product within the period subject to Admission Temporary. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

4.1. The importer must present the respective proof of export within a maximum period of 10 (ten) business days from the shipment of the goods abroad. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

5. The nationalization of goods or products admitted under the Special Customs Regime for Temporary Admission that does not comply with current health legislation is prohibited. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION III

CUSTOMS WAREHOUSE

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

6. The application of the Special Customs Warehousing Regime to the import of goods and products belonging to the following classes and categories is prohibited: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) substances and medicines subject to special control, contained in the Procedures 1 and 1-A, of Chapter XXXIX, of this Resolution; **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

b) human cells and tissues for therapeutic purposes; **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

c) bulk, semi-finished or finished medicines belonging to the categories of blood products and biologicals, and the raw materials that comprise them, contained in Procedures 2, 2-A, 2-B and 2-C, of Chapter XXXIX of this Resolution;
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

d) thalidomide and medicines based on this active ingredient. **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

6.1. Imports destined for public health programs, linked to the Ministry of Health and State and Municipal Secretariats, will be exempt from the provisions of subparagraph “c” of item 7 of this Section. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

7. The nationalization of goods or products imported under the Special Customs Warehousing Regime permission must be subject to health inspection, in accordance with the criteria in Chapter XXXIX of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION IV

FRACTIONAL DELIVERY

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

8. The import of goods or products under sanitary surveillance with fractional delivery, if the sanitary conditions are met, will be subject to the granting of Import Licensing with reservations by SISCOMEX, by the sanitary authority, upon arrival of the first imported fraction. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

8.1. The fractional imports referred to in item 9 of this Section must be communicated to the health authority at least 12 (twelve) hours in advance of the estimated date and time of their arrival. **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

8.2. Communication within a period shorter than that indicated in subitem 9.1 of this Section will subject the importer to applicable health sanctions. **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

8.3. The reservation referred to in item 9 of this Section must be recorded in the field referring to the Import Licensing status in SISCOMEX, with the following text: “PRODUCT UNDER FRACTIONAL DELIVERY. THE RELEASE FOR DISPLAY OR DELIVERY FOR CONSUMPTION OF INTEGRAL FRACTIONAL SHIPMENTS OF THIS

IMPORT LICENSING WILL BE GIVEN UPON SATISFACTORY INSPECTION BY THE HEALTH AUTHORITY”. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

9. The import referred to in this Section must be accompanied by a declaration from the importer taking responsibility for communicating the entry of each fraction of the total goods or products indicated in the Import Licensing, signed by the company's legal representative. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION V

ATA CARNET

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

10. The customs regime for the temporary admission of goods transported under the ATA Carnet, provided for in Decree no. 7,545, of August 2, 2011, which promulgates the Istanbul Convention, will be applied as provided in this Section.
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

11. They may be subject to the regime referred to in this Section, under the terms established in Annexes B.1, B.5 and B.6 of Decree no. 7,545, of August 2, 2011, the following goods and products under health surveillance regime: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Goods and products subject to the health surveillance regime intended for exhibitions, fairs, congresses or similar events; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Health products and in vitro diagnostic products intended for educational, scientific or cultural purposes; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) Goods and products subject to the health surveillance regime for sporting purposes, as long as the quantity is compatible with personal use. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

12. The inspection and release by the health authority of goods transported under the terms of Decree no. 7,545, dated August 2, 2011, will be carried out based exclusively on what constitutes the ATA Carnet. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) The ATA Carnet must be presented by the importer or his representative to the health authority at the place of customs clearance; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Physical verification of the merchandise will only be carried out when the health authority considers that this procedure is necessary; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) verification of compliance with the sanitary conditions for granting the regime, the health authority will affix a stamp and signature if there is an appropriate field on the entry voucher that makes up the ATA Carnet, considering the asset ready to be delivered to its beneficiary. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

13. The entry into the national territory of medical equipment not regularized by ANVISA, intended for exhibition at fairs, congresses or similar events, may also be subject to the ATA Carnet regime. **(Wording given by Resolution –
DRC nº 208, of 5 de janeiro of 2018)**

13.1 The medical equipment referred to in this item, during its stay in the national territory, must be under the assistance of a responsible technical professional, and the professional training of the technical responsible must meet the requirements contained in the relevant health legislation in force. **(Wording given by Resolution –
DRC nº 208, of 5 de janeiro of 2018)**

14. A natural or legal person who appears on the ATA Carnet as the holder is considered a beneficiary of the regime. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

15. The beneficiary may bring to the country only part of the goods described in the General List contained in the ATA Carnet. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

16. The health authority's statement will have effects on all assets of health interest described in the General List of the ATA Carnet. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

17. Goods that, during their stay in the country: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)** cannot be admitted or maintained under the regime referred to in this Section.

a) are subject to or undergo any change, with the exception of normal depreciation resulting from their use; or **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

b) are subject to being consumed. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

18. The import of professional materials, for purposes subject to health surveillance, under the regime of this Section, is prohibited. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

SECTION VI

FREE STORE

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

19. The import for display for sale or delivery for consumption of goods or products under sanitary surveillance in duty-free stores must comply with the relevant sanitary requirements, including: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Conditions of use and consumption described by the manufacturer; **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

b) Expiry date, if present on the packaging; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) Storage in an appropriate environment, in order to guarantee and maintain its identity and quality standards. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

20. Products on display in duty-free stores do not require formal regularization with the SNVS. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

21. The good or product displayed for sale or delivered for consumption in a Free Store may be subject to fiscal or control analysis, in accordance with this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

22. It will be mandatory in Duty Free Stores to maintain information on goods or products under health surveillance, by class, commercial name, quantity, batch or batch number, name of the manufacturer and identification of the buyer, for a period of 5

(five) years from the date of its delivery for sale or its exposure to consumption.

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

~~**CHAPTER XXIX**~~

~~**FREE STORE**~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~1. The exhibition for sale or delivery for consumption of imported goods or products in Duty Free Stores, as well as those offered on international flights by national airlines, will be subject, where applicable, to the relevant health requirements.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~1.1. The provisions of this item will be included, in particular:~~ **(Repealed by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

~~a) expiration date and conditions of use and consumption of goods or products that do not pose any risk or harm to health;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~b) display of goods or products in an appropriate environment to guarantee and maintain their identity and quality standards;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~c) obligation of the company that sells products in the areas of ports, airports and borders to have Operating Authorization for the import activity;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~d) obligation of the company that stores goods or products to supply duty-free stores in areas of ports, airports and borders of Operating Authorization for the storage activity, as well as complying with the relevant health legislation regarding Good Storage Practices.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~1.2. The formal registration or regularization of the product in the National Health Surveillance System will be excluded from the provisions of this item.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~2. The good or product displayed for sale or delivered for consumption in a Free Store may be subject to fiscal or control analysis, in accordance with this Regulation.~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~3. It will be mandatory for Duty Free Stores to maintain information on goods or products under health surveillance by class, commercial name, quantity, batch or batch number, name of the manufacturer and identification of the buyer, for a period of 5 (five) years~~

~~from the date of its delivery for sale or its exposure for consumption.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

CHAPTER XXX

PRODUCTS INTENDED FOR INITIAL SUPPLY AND NURSE REPLACEMENT, PHARMACY OR ON-BOARD MEDICAL SET OR PROVISION OF SERVICES INTERNSHIPS OF LAND VEHICLES THAT OPERATE COLLECTIVE TRANSPORTATION INTERNATIONAL OF PASSENGERS, OR OF VESSELS AND AIRCRAFT

SECTION I

MEDICINES, MEDICAL PRODUCTS AND PRODUCTS FOR INTEGRAL DIAGNOSIS VITRO

1. The import of products belonging to the classes of medicines, medical products and in vitro diagnostic products intended for the initial supply and replenishment of infirmary, pharmacy or medical suite on board land vehicles that operate international public transport of passengers, or of vessels and aircraft, must be subject to the express and favorable statement of the competent health authority.

1.2. Only goods may be imported for the purposes of this section.
or products in finished product form.

~~2. Sanitary release will only occur after inspection of the imported goods or products by the sanitary authority in office at the customs clearance location, in accordance with this Regulation.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

3. The import of products belonging to the classes of medicines that contain narcotic or psychotropic substances, included in Ordinance SVS/MS No. 344, of 1998, may only have customs clearance at entry and clearance points in the national territory authorized for this purpose, in accordance with the relevant health legislation.

4. The products covered by this Section will be exempt from registration or formal regularization in the National Health Surveillance System, without exempting them from complying with other applicable health requirements.

4.1. At the discretion of the health authority, the products covered by this Chapter will be subject to fiscal and control analysis, in accordance with this Regulation.

5. Commercialization and change of purpose informed in the
procedure for import referred to in this Section.

SECTION II

OF FOOD, SANITIZERS, PERSONAL HYGIENE PRODUCTS, PERFUMES AND COSMETICS INTENDED FOR INTERNAL CONSUMPTION OR THE PROVISION OF SERVICES

~~6. The import of products belonging to the classes of personal hygiene products, sanitizing products or foods, intended for consumption or the provision of onboard services on vessels, aircraft and land vehicles that operate international collective passenger transport, must be subject to inspection of ANVISA by the competent authority at the place of clearance, upon presentation of a Petition for Inspection and Sanitary Release provided for in subitem 1.2. of Chapter II.~~

6. The import of products belonging to the classes of personal hygiene products, sanitizing products or foods, intended for consumption or the provision of onboard services on vessels, aircraft and land vehicles that operate international collective passenger transport, must be subject to inspection of ANVISA, upon presentation of a Petition for Inspection and Health Release provided for in subitem 1.2 of Chapter II of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

6.1. The petition referred to in this item must be supported by the competent entry registration document into the national territory and by a document signed by the importer's legal representative, containing the following information:

a) name of the transport company;

b) country of flag of the vessel or country to which the company is linked air or land;

c) name of the port or airport located in the national territory where the supply will take place;

d) identification of the means of transport intended for the product, name or prefix;

e) declaration of non-use of goods or products for purposes other than those indicated for import.

~~6.2. The declaratory document with the information listed in the previous subitem must be presented with signature recognition at a notary's office.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

7. The import referred to in this Section will be exempt from authorization of non-external shipment.

SECTION III

BRAZILIAN FLAG VESSEL, FLAG VESSEL FOREIGN UNDER CHARTER OR LEASE FROM BRAZILIAN COMPANY AND AIRCRAFT PART OF THE AIR FLEET OF A BRAZILIAN COMPANY

8. The import of products belonging to the class of medicines, medical products and in vitro diagnostic products, not regularized with the National Health Surveillance System-SNVS, in accordance with this Section, for supply and replacement of Brazilian-flagged vessels, vessels of foreign flag under charter or lease from a Brazilian company and an aircraft that is part of the air fleet of a Brazilian company, must submit to a prior, conclusive and satisfactory opinion, from the competent technical area of ANVISA, at its headquarters, by submitting a Petition for Inspection and Health Clearance provided for in subitem 1.2. of Chapter II.

8.1. The import referred to in this Section will take place exclusively through Siscomex.

9. The import referred to in this Section will be exempt from authorization of non-external shipment.

9.1. The import of products belonging to the classes of medicines included in Procedures nº 1, nº 1-A, nº 2, nº 2-A, 2-B, 2-C and nº 3, of the Chapter XXXIX of these Regulations.

SECTION IV

FOREIGN FLAG VESSEL AND AIRCRAFT OR LAND VEHICLE MEMBERS OF THE FLEET OF A FOREIGN COMPANY, WHICH OPERATES TRANSPORTATION INTERNATIONAL COLLECTIVE OF PASSENGERS, IN TRANSIT THROUGH THE TERRITORY NATIONAL

~~10. The import of products belonging to the class of medicines, medical products and in vitro diagnostic products, for supply and replacement of a land vehicle that is part of the fleet of a foreign company, which operates international public transport of passengers, or of a flagged vessel or aircraft foreign national, must submit to ANVISA inspection by the competent authority at the place of clearance by presenting a Petition for Inspection and Sanitary Clearance provided for in subitem 1.2. of Chapter II.~~

10. The import of products belonging to the classes of medicines, medical products and in vitro diagnostic products, for supply and replacement of a land vehicle that is part of the fleet of a foreign company that operates international public transport of passengers, or of a foreign-flagged vessel or aircraft , must submit to ANVISA inspection, through the

presentation of a Petition for Inspection and Health Release provided for in subitem 1.2. of Chapter II of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

10.1. The petition referred to in this item must be supported by the competent entry registration document into the national territory and by a document signed by the importer's legal representative, containing the following information:

a) name of the transport company;

b) country of flag of the vessel or country to which the company is linked air or land;

c) name of the port or airport located in the national territory where the supply will take place;

d) identification of the means of transport intended for the product, name or prefix;

e) declaration of non-use of products for purposes other than those indicated for import.

~~10.2. The declaratory document with the information listed in the previous subitem must be presented with signature recognition at a notary's office.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

11. The import of medicines that are part of Procedures 1, 1-A and 3 of Chapter XXXIX of this Regulation will be excluded from the provisions of the previous item, which must undergo a prior, conclusive and satisfactory opinion from the competent technical area of the ANVISA, at its headquarters.

11.1. The import of narcotic, psychotropic medicines and those containing precursor substances in their composition, as referred to in Ordinance SVS/MS nº 344, of 1998 and its amendments, will take place in accordance with current legislation.

CHAPTER XXXI

TRANSPORTATION, MOVEMENT AND STORAGE OF GOODS AND PRODUCTS IMPORTED

SECTION I

GENERAL PROVISIONS

1. The transportation, movement and storage of goods or products imported under health surveillance will take place subject to compliance with Good

Practices, aimed at maintaining its nature, integrity, identity and quality, so that:

a) prevent or avoid any accidents or damages;

b) meet the packaging and storage temperature specifications, tolerated humidity levels, sensitivity to light, among others, defined by the manufacturer, or in accordance with health legislation;

c) place them in satisfactory hygiene and disinfection environments, in order to segregate incompatible loads.

2. The release of goods or products under health surveillance that are transported, moved or stored in environmental conditions that do not comply with the technical specifications, indicated by the manufacturer or provided in the light of regularization before the National Health Surveillance System - SNVS, will not be authorized.

3. The conditions identified in the previous item will imply:

a) when importing through SISCOMEX, upon rejection of the Import Licensing;

b) when importing by other methods, the non-authorization of import will take place using a specific document;

4. Non-authorization of import must be communicated to the Brazilian Federal Revenue Secretariat - Ministry of Finance, through its local body, for subsequent consultation with the health authority regarding the movement or destination of that product.

SECTION II

TRANSPORTATION

5. The goods or product will be transported by companies regulated in the National Health Surveillance System, in terms of Operating Authorization, Special Operating Authorization and health license, for the respective activity and class of product.

6. The Bill of Lading issued, for air, water or land cargo, must include the environmental conditions for transport and storage, such as temperature, humidity and light and others provided for in health legislation, when applicable.

7. The international air or water transport company for goods or products must present a copy of the Cargo Manifest transported, with expected disembarkation, when requested by the health authority.

8. The international land transport company of goods or products must present, when transiting through a border customs station, the International Cargo Manifest or Customs Transit Clearance, when requested by the health authority in place.

SECTION III

FROM STORAGE

9. The storage of the good or product will be carried out by companies regularized in the National Health Surveillance System, in terms of Operating Authorization, Special Operating Authorization and health license, for the respective activity and class of product.

9.1. For the purposes of this item, storage is considered to be the storage of goods or products under sanitary surveillance, regardless of their duration and temporary disposition, the nature and commercial purpose of the legal entity carrying out this activity, under the conditions and sanitary requirements laid down. in this Regulation, in other health standards, and, alternatively, by the data provided by the importer and manufacturer, for their guarantee and maintenance.

~~**CHAPTER XXXII**~~

~~**EXPORTED GOODS OR PRODUCTS PRODUCED IN THE NATIONAL TERRITORY AND RETURNED**~~

~~1. The exported good or product under health surveillance that, for whatever reasons, is returned to the national territory, must comply with the provisions of this Regulation.~~

~~1.1. This item includes the import of representative samples of the good or product exported under rejection for quality control purposes in the national territory.~~

~~2. The good or product must have Import Licensing registration with SISCOMEX - Import Module, being exempt from requesting authorization for shipment abroad from the health authority in office at the place of customs clearance.~~

~~3. The importer must present to the health authority in office at the customs clearance location the information regarding the return and destination of the good or product, as well as the Analytical Quality Control Report carried out abroad, if applicable.~~

~~4. The health authority will decide on the granting of Import Licensing with reservations and issuance of the relevant legal terms~~

~~of seizure or seizure and interdiction, as applicable, for the purposes of fiscal analysis or control, and of custody and responsibility, if applicable.~~

~~4.1. The legal term referred to in this item will be drawn up simultaneously with the collection of the product sample.~~

~~4.2. The reservation referred to in this item must be registered with the following text: "PRODUCT EXPORTED WITH RETURN TO THE NATIONAL TERRITORY UNDER THE GUARD AND RESPONSIBILITY OF THE IMPORTER. RELEASE FOR DISPLAY OR DELIVERY FOR CONSUMPTION WILL BE TAKEN UPON PRESENTATION OF PRIOR, CONCLUSIVE ANALYSIS AND SATISFACTORY OF THE LABORATORY REPORT OF THE PRODUCT BY THE HEALTH AUTHORITY IN OPERATION AT THE CUSTOMS CLEARANCE PLACE".~~

~~4.3 The importing company will be notified to carry out the quality control analyzes of the samples described in subitem 1.1 and present the laboratory analysis report to the health authority.~~

~~4.4 In case of an unsatisfactory analysis report, the national and international distribution map of the analyzed batch and proof of return of the entire exported quantity must be presented.~~

~~5. Health release will only occur after satisfactory analysis of the product's laboratory report by the health authority, in office at the customs clearance location.~~

~~5.1. Physical inspection of goods or products may be carried out at the place of storage.~~

~~6. When it is impossible to carry out fiscal or control analysis in official laboratories, it will be possible to carry out analytical quality control tests in the manufacturer's own laboratory or outsourced by it, in accordance with this Regulation and in accordance with relevant health legislation from which is justified and authorized by the ANVISA technical sector at its headquarters.~~

~~7. The omitted cases relating to imports referred to in this Chapter will be examined jointly by the General Management of Ports, Airports and Borders - GGPAF, and by the competent technical sector of ANVISA, at its headquarters.~~

CHAPTER XXXII

EXPORTED GOODS OR PRODUCTS PRODUCED IN THE NATIONAL TERRITORY AND RETURNED

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

1. The exported good or product under health surveillance that, for any reason, is returned to the national territory must have a Licensing registration

of Importation with SISCOMEX – Import Module, being exempt from authorization to board abroad. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

1.1. Item 1 of this Chapter includes the import of representative samples of the exported good or product, under rejection, for quality control purposes in the national territory. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2. The importer must present to the health authority information regarding the return and destination of the good or product, as well as the Analytical Quality Control Report carried out abroad, if applicable. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

3. The health authority will decide whether to grant Import Licensing, grant a Term of Custody and Responsibility or issue legal terms of seizure or interdiction, as the case may be, for fiscal analysis or control purposes. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

3.1 The health authority may collect samples and send them to official or accredited laboratories. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

3.1.1. If it is impossible to carry out fiscal or control analysis in official laboratories, analytical quality control tests will be permitted in the manufacturer's own laboratory or outsourced by them, in compliance with the relevant health legislation, as long as it is justified and authorized by the competent technical sector. of ANVISA at its headquarters. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

3.2. The approval with a Term of Custody and Responsibility must be registered in Siscomex with the following text: “PRODUCT EXPORTED WITH RETURN TO THE NATIONAL TERRITORY, UNDER THE GUARD AND RESPONSIBILITY OF THE IMPORTER. RELEASE FOR DISPLAY OR DELIVERY FOR CONSUMPTION WILL BE TAKEN UPON PRESENTATION OF A CONCLUSIVE AND SATISFACTORY LABORATORY REPORT ON THE PRODUCT”. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

4. When a laboratory analysis is determined by the health authority, in the event of an unsatisfactory report, the national and international distribution map of the analyzed batch and proof of return of the entire exported quantity must be presented.
(Wording given by Resolution – RDC nº 208, of January 5, 2018)

5. Any omitted cases relating to imports covered by this Chapter will be examined jointly by the General Management of Ports, Airports and Borders

(GGPAF), and by the competent technical sector of ANVISA, at its headquarters. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

CHAPTER XXXIII

RETURN/REFECTION OF PROHIBITED IMPORTED GOODS OR PRODUCTS

1. The request for partial or total return abroad of imported goods or products under health surveillance, under seizure or interdiction, due to non-compliance with the health requirements set out in this Regulation or in other health legal diplomas in force, must be submitted to the health authority in office at the place of customs clearance.

1.1. ANVISA's Coordination of Ports, Airports and Borders will be responsible for the conclusive technical analysis of the request referred to in this item;

1.2. In cases of suspicion or compromise of the product in terms of its integrity and quality, the General Management of Ports, Airports, Borders and Customs Areas must be immediately notified.

2. When customs clearance of the substances included in the lists of Ordinance SVS/MS nº 344/98 and its updates, as well as the medicines containing them, are not carried out, they will be returned or returned to the country of origin and the company must request cancellation of documentation relating to import.

3. The importer must present proof of return of the merchandise abroad to the health authority in office at the customs clearance location, within a maximum period of 10 (ten) business days from the shipment of the good or product.

4. All obligations and charges related to the return, partial or total, of the good or product abroad will be borne by the importer.

~~CHAPTER XXXIV~~

~~RETURN OF GOODS OR PRODUCTS EXPORTED FOR THE PURPOSE OF PROVIDING SERVICES ABROAD OR REPAIR, REPAIR OR RESTORATION~~

~~1. The exporter of goods or products under sanitary surveillance, for the purpose of providing services abroad or repairs with subsequent return to the national territory, must, prior to their shipment abroad, present them to the sanitary authority, in office at the customs clearance location. , Petition for Inspection and Health Release provided for in Chapter II, subitem 1.2., accompanied by the following documents:~~

~~a) Declaration in accordance with Chapter XXXV;~~

~~b) commercial invoice in two copies, original and copy for authentication, which will be retained, or declaration of ownership of the good or product in which its technical specifications are described, such as commercial name, brand, model and manufacturer, signed by the responsible person, person physical or legal entity, in which case, by its legal representative;~~

~~c) Official document proving the departure of the good or product.~~

~~2. The request for import release regarding the return of the goods and products covered by this Chapter will be made through the presentation to the health authority, in office at the customs clearance location, of the Petition for Inspection and Health Release provided for in the Chapter II, subitem 1.2, instructed by the Declaration of Exit of the Good or Product Abroad.~~

~~3. The imports referred to in this Chapter will be exempt from authorization for shipment abroad.~~

CHAPTER XXXIV

RETURN OF GOODS OR PRODUCTS EXPORTED FOR THE PURPOSE OF PROVIDING SERVICES OR REPAIR OR REPAIR OR RESTORATION ABROAD

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

1. The request for import release regarding the return of the goods and products referred to in this Chapter will be made through the presentation of the Petition for Inspection and Sanitary Release provided for in Chapter II, subitem 1.2, accompanied by the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) purchase invoice or declaration of ownership of the good or product, in which its technical specifications are described, such as commercial name, brand, model and manufacturer, signed by the person responsible, an individual or legal entity, in the latter case, by their representative Cool; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Export declaration or equivalent customs document proving the departure of the good or product. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2. The imports referred to in this Chapter will be exempt from authorization for shipment abroad. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XXXV

~~DECLARATION OF GOOD OR PRODUCT LEAVING ABROAD~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

CAPÍTULO XXXV
DECLARAÇÃO DE SAÍDA DE BEM OU PRODUTO PARA O EXTERIOR

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA		
DECLARAÇÃO DE SAÍDA DE BEM OU PRODUTO PARA O EXTERIOR (**DSE**)	Unidade ANVISA de Saída do País	PROTOCOLO Número __/__/__
1. DADOS DO EXPORTADOR:		
1.1. CPF OU CNPJ:		
1.2. RAZÃO SOCIAL / NOME COMPLETO:		
1.3. ENDEREÇO COMPLETO		
RUA/AVENIDA:	Nº.	COMPLEMENTO:
BAIRRO:	CEP:	
MUNICÍPIO:	UF:	
2. ESPECIFICAÇÃO DO BEM OU PRODUTO:		
2.1. DESCRIÇÃO MARCA COMERCIAL/MODELO:		REGULARIZAÇÃO ANVISA:
OBS: DECLARAÇÃO VÁLIDA POR MARCA COMERCIAL/MODELO		
2.2. QUANTIDADE:		
2.3. PESO (KG):		
2.4. INFORMAÇÕES COMPLEMENTARES:		
3. DADOS DA EXPORTAÇÃO:		
3.1. DATA DO EMBARQUE:		
3.2. DESTINO:		
OBS: INFORMAR EMPRESA E ENDEREÇO COMPLETO NO PAÍS DE DESTINO		
3.3. FINALIDADE DE EXPORTAÇÃO:		
LOCAL E DATA:	ASSINATURA EXPORTADOR (RESPONSÁVEL/REPRESENTANTE LEGAL)	
4. USO EXCLUSIVO ANVISA:		
4.1. DATA, NOME, SIAPE E ASSINATURA DA AUTORIDADE SANITÁRIA SAÍDA		4.2. DATA, NOME, SIAPE E ASSINATURA DA AUTORIDADE SANITÁRIA RETORNO
4.1. DATA, NOME, SIAPE E ASSINATURA DA AUTORIDADE SANITÁRIA SAÍDA		4.2. DATA, NOME, SIAPE E ASSINATURA DA AUTORIDADE SANITÁRIA RETORNO

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XXXVI

PENALTIES AND RESTRICTIONS

SECTION I

GENERAL PROVISIONS

1. Non-compliance or non-compliance with the provisions of this Regulation will subject the importer and the person responsible for regulating the product to the penalties and restrictions provided for in health legislation, without prejudice to the exercise of the powers of other public bodies.

1.1. Depending on the need and adequacy of penalties and restrictions for the prevention and promotion of public health, in the event of joint application of measures with the customs authority, the latter may promote product storage.

1.2. The provisions of the previous item do not exempt the health authority from applying the relevant penalties and restrictions through the drafting of legal terms.

SECTION II

SEIZURE, PRECAUTIONARY INTERDICTION AND DISPOSAL

2. The seizure of samples for analysis, fiscal or control purposes will be accompanied by a Term of Seizure.

3. Goods or products will be subject to control or fiscal analysis by taking samples whenever the health authority deems it necessary, when it is mandatory or when suspected of contravening health legislation.

3.1. The provisions of the previous item are excepted for goods or products imported by individual whose number makes this procedure unfeasible.

4. In cases where signs of alteration, adulteration or contravention of health legislation are blatant, the products will be subject to preventive interdiction, through the drawing up of a Seizure and Interdiction Term for the imported batch or batch.

4.1. The provisions of this item will include the following goods or products:

a) in which damage is found in their packaging, with suspicion of compromise of its integrity;

4.2. The precautionary interdiction will last for the period necessary to carry out tests, tests, analyzes or other required measures, limited to the period indicated for its execution.

5. Goods or products will be subject to prohibition in the event of a condemnatory laboratory result or finding that they are contrary to health legislation, through a Prohibition Term, including closure of the establishment, when necessary.

6. Goods or products not provided for in the import document will be subject to seizure and interdiction, or interdiction, as the case may be.

7. In the event of alteration, adulteration or falsification of goods or products that result in inappropriate use or consumption, they will be subject to destruction, upon drawing up a Declaration of Inutilization, under the responsibility of the importer.

7.1. The provisions of this item will include goods or products subject to health inspection from international donations.

7.2. Technical, intermediate and final procedures related to destruction must occur with the consent and presence of the health authority.

7.3. The treatment and final disposal methods related to the destruction of any and all goods or products of interest to health surveillance, even if not subject to express control of import modalities, must comply with the environmental control provisions of the federated unit in which they are carried out.

SECTION III

GUARDIANITY AND RESPONSIBILITY

8. Goods or products under health surveillance, subject to fiscal or control analysis, upon entry into the country may be allowed to leave the authorized customs area, with reservations, subject to the importer being subject to the Term of Custody and Responsibility.

8.1. The reservation referred to in this item must be registered in the field referring to the status of the Import License in SISCOMEX, or in a specific import document, with the following text: "PRODUCT UNDER SANITARY REQUIREMENT. RELEASE TO
INDUSTRIALIZATION, DISPLAY FOR SALE OR DELIVERY FOR CONSUMPTION WILL TAKE PLACE THROUGH EXPRESS STATEMENT FROM THE HEALTH AUTHORITY".

9. It will be a mandatory prerequisite for the custody and responsibility of the good or product in accordance with this Section, its storage in an establishment holding a Health License or equivalent authorization, issued by the health authority of the State, Municipality or the Federal District, and, when applicable, authorized by ANVISA regarding the Operating Authorization or Special Operating Authorization, for the respective activity and product class.

10. The release of the good or product and the obligations arising from the Term of Custody and Responsibility will take place after physical inspection, or adoption of other measures deemed necessary, by the Coordination of Health Surveillance of Ports, Airports and Borders of the federated state from the storage location.

10.1. The statement referred to in this item must be registered on the document itself. term.

10.2. Other necessary measures for the purposes of this item will be considered, the subsidiary inspection of the good or product, physical installations and documents of the company's technical records to resolve the health requirement determined by the health authority, including in other federated units.

CHAPTER 37

FINAL DISPOSITIONS

1. The import of goods or products under health surveillance through diplomatic or consular mail will be prohibited, depending on the concept of this institute, in accordance with the relevant legislation.

1.1. Failure to comply with or disregard the provisions of this item will subject the importer to the provisions of this Regulation.

~~2. Imports with a purpose declared by the importer, not subject to sanitary intervention by ANVISA, whose tariff classification - NCM/SH - integrates the list and procedures provided for in Chapter XXXIX of this Regulation, must be approved by the Import Licensing exercised in accordance with with the authority of ANVISA, at the customs clearance location.~~

~~2.1. The import referred to in the previous item must have the purpose and use of the product registered in the "complementary information" field of the Import Licensing.~~

~~2.2. Compliance in the fiscal year referred to in this item will be limited to the documentary analysis presented by the importer through the Petition for Health Inspection provided for in Chapter II, subitem 1.2., instructed by the Term of Responsibility according to Chapter XXXVIII.~~

~~2.2.1. The Term of Responsibility referred to in this sub-item must be signed by the legally responsible and/or technically responsible person, with notarized signature and accompanied by a satisfactory and conclusive statement from the consenting public body, when applicable.~~

~~2.2.2. The goods or products not subject to sanitary intervention by ANVISA as referred to in this item, will not be considered as a possibility of collection on imports of the Health Surveillance Inspection Fee with ANVISA, in accordance with the legal enumeration of goods and products under its exclusive health control and inspection.~~

~~2.3. The substances "TRICHLOROETHYLENE, DISULFIRAM or LITHIUM (METALLICS AND THEIR SALTS)" provided for in Ordinances SVS/MS nº. 344/98, when used for purposes other than therapeutic or medicinal purposes, provided that the import to a legal entity responsible for the production of products without therapeutic or medicinal purposes in a national industrial park is proven;~~

~~2.3.1. The importer referred to in the previous sub-item must present to the health authority at the place of clearance a petition for health inspection provided for in Chapter II, sub-item 1.2. instructed by the Term of Responsibility referred to in Chapter XXXVIII;~~

~~2.3.2. The exercise referred to in this subitem will be limited to the analysis of the documentation presented by the importer.~~

~~2.4. The approval of Import Licensing will be subject to reservations, upon satisfactory analysis of the information required by the health authority.~~

~~2.5. The reservation referred to in the previous item must be registered in the field referring to the import licensing status in SISCOMEX with the following text: "GOOD OR PRODUCT IMPORTED FOR PURPOSE IS NOT SUBJECT TO HEALTH INTERVENTION BY ANVISA, ACCORDING TO THE RESPONSIBILITY TERM PRESENTED BY THE IMPORTER" .~~

2. Imports with a purpose declared by the importer, not subject to sanitary intervention by ANVISA, whose tariff classification - NCM/SH - integrates the list and procedures provided for in Chapter XXXIX of this Resolution, must be subject to inspection by ANVISA, upon presentation of Petition for Health Inspection and Release, provided for in subitem 1.2 of Chapter II, instructed by the Term of Responsibility described in Chapter XXXVIII of this Resolution. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.1. The Term of Responsibility referred to in item 2 of this Chapter will be signed by the legal and/or technical responsible of the Importer and must describe the purpose and use of the imported product. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.2. Goods or products not subject to sanitary intervention by ANVISA referred to in item 2 of this Chapter, will not be considered as a possibility of collection, upon import, of the Sanitary Surveillance Inspection Fee with ANVISA. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.3. Substances included in the Lists of Ordinance SVS/MS nº 344, of May 12, 1998, and its updates, with exemption from control provided for in that same Ordinance, when used exclusively for legitimate industrial purposes, other than therapeutic or medicinal purposes, are not subject ANVISA's health intervention. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

2.4. Import Licensing will be granted after satisfactory analysis of the information required in this Resolution, with registration, in the field referring to the import licensing status in SISCOMEX, of the following text: “GOOD OR PRODUCT IMPORTED FOR PURPOSE IS NOT SUBJECT TO HEALTH INTERVENTION BY ANVISA , ACCORDING TO THE RESPONSIBILITY TERM PRESENTED BY THE IMPORTER”. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

3. In addition to the procedures provided for in this Regulation, the measures and formalities provided for in other legal and regulatory provisions, or others determined at any time by the health authority, must be observed and complied with, including with regard to the temporary or definitive suspension of imports, for reasons grounds for prevention and precaution of the harmfulness of the good or product to individual and collective human health.

4. Information relating to the import of goods or products, in accordance with this Regulation, must faithfully correspond to that found during inspection and health inspection.

5. Measures for carrying out inspection of goods or products under sanitary requirements, in accordance with this Regulation, in external areas not included in the import process or outside customs areas, may be carried out by the respective instance of the Unified Health System in that the product is found, in accordance with the executive-level integration of health actions, as adopted and agreed by ANVISA, at its headquarters.

6. Goods or products under health surveillance seized or interdicted by other public authorities, whether health or otherwise, during the fiscal year of the import process, in accordance with this Regulation, must undergo a prior technical opinion from the respective Health Surveillance Coordination of Ports, Airports and Borders where it is seized and interdicted, with a view to demonstrating its identity and quality standard, and its sanitary release, if applicable.

6.1. The provisions of this item will include goods or products under health surveillance intended for donation, auction or any other event that allows their potential or actual contact, exposure or consumption, directly or indirectly, by human beings.

7. All measures, formalities and health requirements for the fulfillment and observance of this Regulation will be carried out in accordance with the technical-normative guidance of the responsible hierarchical sectors, both the General Management of Ports, Airports and Borders, and the General Managements, competent technical sectors , as well as the Collegiate Board of Directors of ANVISA, in the person of its Chief Executive Officer.

~~8. The import of goods or products not regularized by ANVISA, linked to the obligation to comply with legal actions granted in the interest of clinical treatment of patients, in which the importing legal entity is the Ministry of Health, State and Federal District or Municipal Secretariats of Health, must have analysis and approval of Import Licensing granted by the health authority in office at the customs clearance location.~~

8. The import of goods or products not regularized by ANVISA, linked to the obligation to comply with legal actions granted in the interest of clinical treatment of patients, in which the importing legal entity is a public institution that is part of the organizational structure of the Unified Health System (SUS), will have automatic approval of import licensing at SISCOMEX, regardless of the performance of any other technical or procedural analysis, and it is the importer's responsibility to guarantee the quality and safety of the products purchased. **(Wording given by Resolution – RDC nº 262, of February 1, 2019)**

9. The importation of medicines referred to in procedures 2, 2-A, 2-B and 2-C of Chapter XXXIX, not regularized by ANVISA, intended for public health programs will be under exclusive authorization by the Collegiate Board of ANVISA, in the person of the President Director.

10. The request for nationalization of a product under health surveillance motivated by the finding of health irregularities, in documentary analysis or physical inspection, when substantiated by technical documentation, must be requested to the Coordination of Ports, Airports, Borders and Customs Areas of the federated unit where the fiscal intervention took place and was subsequently analyzed, when appropriate, by the General Management of Ports, Airports, Borders and Customs Areas and/or by the competent technical areas of ANVISA, at its headquarters.

10.1. In view of the provisions of the item above, a conclusive opinion must be prepared for approval by the General Management involved or by the ANVISA Collegiate Board, when appropriate.

~~11. The import of human hair without hair bulb, intended for the manufacture of wigs and extensions, will take place through Import Licensing registration with SISCOMEX, in accordance with Chapter XXXIX of these Regulations or Express Shipping.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~11.1. The product covered by this item must be presented in intact packaging, and identified on its label with the relevant technical information, such as sterilization, disinfection and disinfestation.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~11.2. The company importing the product covered by this item will be exempt from Operating Authorization with ANVISA.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

12. At the discretion of the health authority, translation may be required, by a signatory duly identified by name, address and Individual Taxpayer Registry (CPF) number, of documents presented in a foreign language, for the purposes of this Regulation.

13. The Regulation of changes in company ownership due to merger, split, incorporation or succession must comply with the provisions of the relevant health legislation.

14. The bodies and entities participating in the consent for the import of goods or products of health interest may, by agreement between the parties, implement and promote agreed measures to achieve the provisions of this Regulation.

14.1. For the purposes of this item, bodies and entities may adopt:

a) harmonious health inspection conduct, by product risk category;

b) collection, transport and laboratory analysis methodology, by category of imported product;

c) definition of laboratory responsible for type of analysis, for the purposes of the provisions of the previous paragraph;

d) human resources training plan;

e) work plan for implementing the harmonized sanitary and phytosanitary inspection system for imported goods or products, and execution schedule.

15. Cases not provided for in this Regulation will be analyzed by the area competent technician from ANVISA, at its headquarters.

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XXXVIII

STATEMENT OF RESPONSIBILITY

IMPORTS NOT SUBJECT TO ANVISA HEALTH INTERVENTION

The natural/legal person _____, declares that the product(s) listed below will be imported, with purpose; _____not subject to fiscal intervention by ANVISA and will be stored, in an area outside the customs area, at the following address:

Item	Name Commercial	Common name or Chemist	No. lots	Amount	Number and Regularization Body, if applicable.
01					
02					

The undersigned assume health responsibility for damage to individual or collective health and the environment resulting from the change in the purpose of the product entering the national territory.

_____

TECHNICAL MANAGER LEGAL REPRESENTATIVE

CR No.

CHAPTER XXXIX

ADMINISTRATIVE PROCEDURES FOR PRODUCT CLASSIFICATION ALONG WITH THE INTEGRATED FOREIGN TRADE SYSTEM

~~SECTION I~~

~~PROCEDURE 1 - GOODS AND PRODUCTS SUBJECT TO SPECIAL CONTROL OF WHICH DEALS WITH ORDINANCE SVS/MS No. 344, OF 1998 AND ITS UPDATES, IN ITS LISTAS "A1", "A2", "A3", "B1", "B2" E "D1"~~

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

SECTION I

PROCEDURE 1 - GOODS AND PRODUCTS SUBJECT TO SPECIAL CONTROL OF WHICH DEALS WITH ORDINANCE SVS/MS No. 344, OF 1998 AND ITS UPDATES, IN ITS LISTAS "A1", "A2", "A3", "B1", "B2", "C3" E "D1"

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

1. The import of goods and products subject to the special control referred to in Ordinance SVS/MS No. 344, of 1998 and its updates, in the form of raw material, semi-finished product or finished product, depending on the classification of the goods and products available on the ANVISA website will be subject to Import Licensing registration with SISCOMEX and favorable prior authorization for shipment, subject to inspection by the health authority before customs clearance.

2. Favorable prior authorization for boarding will be given upon manifestation from the competent technical area of ANVISA, at its headquarters in Brasília, DF.

2.1. It will be up to the interested company to submit a request to ANVISA for authorization to board abroad, by filling out a Petition for Authorization to Board Abroad.

~~3. Goods and products subject to the special control referred to in Ordinance SVS/MS No. 344, of 1998 and its updates, may only enter the national territory through the following ports and airports:~~ **(Repealed by Resolution – RDC No. 208, of 5 January 2018)**

~~a) Port of Rio de Janeiro, Rio de Janeiro, RJ;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~b) Rio de Janeiro International Airport - Maestro Antônio Carlos Jobim, Rio de Janeiro, RJ;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~c) Port of Santos, Santos, SP;~~ **(Revoked by Resolution – RDC nº 208, of 5 January 2018)**

~~d) São Paulo International Airport - Governador André Franco Montoro Airport, Guarulhos, SP.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

4. Mandatory documentation will be created for presentation to the authority sanitary facility where the raw material, input or medicine will be cleared:

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **~~(Revoked by Resolution – RDC nº 208~~, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **~~(Revoke~~d by Resolution – RDC nº 208, of January 5, 2018)**

d) Import Authorization or No Objection Certificate issued by the competent area at ANVISA (2nd original copy or copy for authentication);

e) Export Authorization or No Objection Certificate (2nd original copy or copy for authentication) issued by the competent authority abroad;

f) Commercial Invoice - "Invoice" (original and copy for authentication);

g) Bill of Laden Cargo (original and copy for authentication);

~~h) Declaration regarding the lots or items, identified alpha-numerically, whatever fits;~~ **~~(Rev~~oked by Resolution – RDC nº 208, of January 5, 2018)**

i) Analytical Quality Control Report, per batch or batch, issued by the manufacturer, except when dealing with imports of primary reference standards;

~~j) Guide for Withdrawal of Substances, Narcotic Medications, or those that determine physical or psychological dependence, in accordance with Chapter V of the Ordinance SVS/MS nº 344, of 1998 and its updates, issued in 6 (six) copies;~~ **~~(Revoked by~~ Resolution – RDC nº 62, of February 11, 2016)**

~~l) Power of attorney from the legal entity holding the regularization of the product with ANVISA to the legal representative, responsible for customs clearance;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

m) Annotation document referring to proof of the docking of the good and product in the storage environment and its respective location, issued by the legal representative of the legal entity managing the customs area where the product is stored.

~~4.1. The documents referred to in paragraphs "d", "e", "h" and "i" must be certified by the technician responsible.~~ **~~(Revoked by Resolution – RD~~C nº 208, of January 5, 2018)**

~~4.2. The agent duly registered with the respective CVPAF of customs clearance will be exempt from presenting the document in item "l".~~ **~~(Revoked by Resolution – RDC nº 208, of Januar~~y 5, 2018)**

~~5. The classification of products covered by this Section is available on the ANVISA website, and produces legal effects for their classification upon import under sanitary approval.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

SECTION II

PROCEDURE 1-A - GOODS AND PRODUCTS SUBJECT TO SPECIAL CONTROL OF WHICH TREATS SVS/MS ORDINANCE No. 344, OF 1998 AND ITS UPDATES, IN ITS LIST "F"

6. The import of products subject to the special control referred to in Ordinance SVS/MS nº 344, of 1998 and its updates, included in List "F", in the form of raw material, semi-finished product or finished product is prohibited. , according to the classification of goods and products available on the ANVISA website, unless intended for teaching and research.

7. The import of goods and products referred to in this Section will be subject to Import Licensing registration with SISCOMEX and favorable prior authorization for shipment, subject to inspection by the health authority before customs clearance.

8. Favorable prior authorization for boarding will be given upon manifestation from the competent technical area of ANVISA, at its headquarters in Brasília, DF.

8.1. The interested company will be responsible for submitting a request for authorization to board abroad to ANVISA, by filling out a Petition for Authorization to Board Abroad.

9. Goods and products subject to the special control referred to in Ordinance SVS/MS nº 344, of 1998 and its updates, included in List "F", may only enter national territory through the following ports and airports:

a) Port of Rio de Janeiro, Rio de Janeiro, RJ;

b) Rio de Janeiro International Airport - Maestro Antônio Airport Carlos Jobim, Rio de Janeiro, RJ;

c) Port of Santos, Santos, SP;

d) São Paulo International Airport - Governador André Franco Montoro Airport, Guarulhos, SP.

10. Mandatory documentation will be created for presentation to the authority sanitary facility where the raw material, input or medicine will be cleared:

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

d) Import Authorization or No Objection Certificate issued by the competent area at ANVISA (2nd original copy or copy for authentication);

e) Export Authorization or No Objection Certificate (2nd original copy or copy for authentication) issued by the competent authority abroad;

f) Commercial Invoice - "Invoice" (original and copy for authentication);

g) Bill of Laden Cargo (original and copy for authentication);

~~h) Declaration regarding the lots or items, identified alpha numerically, whatever fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

i) Analytical Quality Control Report, per batch or batch, issued by the manufacturer, except when dealing with imports of primary reference standards;

~~j) Guide for Withdrawal of Substances, Narcotic Medications, or those that determine physical or psychological dependence, in accordance with Chapter V of the Ordinance SVS/MS nº 344 of 1998 and its updates, issued in 6 (six) copies;~~ **(Revoked by Resolution – RDC nº 62, of February 11, 2016) (Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~l) Power of attorney instrument from the legal entity holding the regularization of the product with ANVISA to the legal representative, responsible for customs clearance;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

m) Annotation document referring to proof of the docking of the good or product in the storage environment and its respective location, issued by the legal representative of the legal entity managing the customs area where the product is stored.

~~10.1. The documents referred to in paragraphs "d", "e", "h" and "i" must be certified by the technician responsible.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~10.2. The agent duly registered with the respective CVPAF of customs clearance will be exempt from presenting the document in item "I".~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~11. The classification of products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon import under sanitary approval.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

SECTION III

PROCEDURE 2 - BLOOD DERIVATIVES

12. The import of blood products in the form of raw material, semi-finished product, bulk product or finished product, as per the framework of the
Products available on the ANVISA website will be subject to Import Licensing registration with SISCOMEX, subject to inspection by the health authority before customs clearance.

~~13. The goods and products referred to in this Section may only enter national territory through the following ports and airports:~~ **(Revoked by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

~~a) Port of Rio de Janeiro, Rio de Janeiro, RJ;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~b) Rio de Janeiro International Airport - Maestro Antônio Airport Carlos Jobim, Rio de Janeiro, RJ;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~c) Port of Santos, Santos, SP;~~ **(Revoked by Resolution – RDC nº 208, of 5 January 2018)**

~~d) São Paulo International Airport - Governador André Franco Airport Montoro, Guarulhos, SP;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~e) Tancredo Neves International Airport, MG;~~ **(Repealed by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

~~f) Porto Alegre International Airport - Salgado International Airport Filho, RS~~; **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~g) Brasília International Airport - Presidente International Airport Juscelino Kubitschek, DF;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~h) Guararapes International Airport - Gilberto International Airport Freire, PE;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~i) Manaus International Airport - Eduardo International Airport Gomes, AM.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~16. Mandatory documentation will be created for presentation to the health authority where the good or product will be released:~~

16. The import process must include the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Declaration regarding the lots or items, identified alphanumerically, whatever fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

g) Analytical Quality Control Report of the active pharmaceutical ingredient and finished product, by batch or batch, issued by the manufacturer, except when dealing with imports of primary reference standards;

h) Certificate of batch release of the finished product (finished), issued by the health authority of the country of manufacture, for blood products, except when dealing with imports of primary reference standards;

~~i) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided in the relevant health legislation, for collection and transportation of products for control analysis, when applicable;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~j) Power of attorney from the legal entity holding the regularization of the product with ANVISA to the legal representative, responsible for customs clearance;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~l) Annotation document referring to proof of the docking of the good or product in the storage environment and its respective location, issued by the legal representative of the legal entity managing the customs area where the good or product is stored.~~ **~~(Revoked by Resolution – RDC nº 599, of February 9, 2022)~~**

~~13.1. When the obligation of exclusive presentation in its original form is not specified~~, ~~the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~13.2. The documents referred to in paragraphs "f" and "g" must be certified by the technician responsible~~ **~~(Re~~voked by Resolution – RDC nº 208, of January 5, 2018)**

~~13.3. The agent duly registered with the respective CVPAF of clearance will be exempt from presenting the document in item "j".~~ **~~(Revoked by Resolution~~ – RDC nº 208, of January 5, 2018)**

~~14. The classification of goods or products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon importation under sanitary approval.~~ **~~(Revoked by Resolution – RD~~C nº 208, of January 5, 2018)**

15. The import of samples of non-regularized medicines, without proof of safety and efficacy, intended for analysis for registration purposes, quality control tests, stability studies, bioequivalence and pharmaceutical equivalence or even testing of equipment participating in the manufacturing process or laboratory, whose composition includes active substances with proven safety and efficacy, must meet the sanitary requirements set out in this procedure, except for those relating to the presentation of the ANVISA registration.

SECTION IV

PROCEDURE 2A - SERA AND VACCINES

16. The import of hyperimmune serums and vaccines in the form of raw material, semi-finished product, bulk product or finished product, according to the classification of products available on the ANVISA website, will be subject to Import Licensing registration at SISCOMEX, submitting subject to inspection by the health authority before customs clearance.

~~17. The goods and products referred to in this Section may only enter national territory through the following ports and airports:~~ **~~(Repealed~~ by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

~~a) Port of Rio de Janeiro, Rio de Janeiro, RJ; (Revoked~~ **by Resolution – RDC nº 208, of January 5, 2018)**

~~b) Rio de Janeiro International Airport - Maestro Antônio Airport Carlos Jobim, Rio de Janeiro, RJ; (Revoke~~**d by Resolution – RDC nº 208, of January 5, 2018)**

~~c) Port of Santos, Santos, SP; (Revoke~~**d by Resolution – RDC nº 208, of 5 January 2018)**

~~d) São Paulo International Airport - Governador André Franco Airport Montoro, Guarulhos, SP; (Revo~~**ked by Resolution – RDC nº 208, of January 5, 2018)**

~~e) Tancredo Neves International Airport, MG; (Repealed by R~~**esolution – DRC nº 208, of 5 de janeiro of 2018)**

~~f) Porto Alegre International Airport - Salgado International Airport Filho, RS; (~~**Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~g) Brasília International Airport - Presidente International Airport Juscelino Kubitschek, DF; (Revo~~**ked by Resolution – RDC nº 208, of January 5, 2018)**

~~h) Guararapes International Airport - Gilberto International Airport Freire, PE; (~~**Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~i) Manaus International Airport - Eduardo International Airport Gomes, AM. (~~**Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~18. Mandatory documentation will be created for presentation to the health authority where the good or product will be released:~~

18. The import process must include the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation; (Revoked by Resolution – RDC nº 208~~**, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits; (Revoke~~**d by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Declaration regarding the lots or items, identified alphanumerically, whatever fits;~~ **~~(Rev~~oked by Resolution – RDC nº 208, of January 5, 2018)**

g) Analytical Quality Control Report of the active pharmaceutical ingredient and finished product, by batch or batch, issued by the manufacturer, except when dealing with imports of primary reference standards;

h) Certificate of batch release of the finished product (finished), issued by the health authority of the country of manufacture, for vaccines and serums, except when dealing with imports of primary reference standards;

~~i) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided in the relevant health legislation, for collection and transportation of products for control analysis, when applicable;~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~j) Power of attorney from the legal entity holding the regularization of the product with ANVISA to the legal representative, responsible for customs clearance;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~l) Annotation document referring to proof of the docking of the good or product in the storage environment and its respective location, issued by the legal representative of the legal entity managing the customs area where the good or product is stored.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~18.1. When the obligation of exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~18.2. The documents referred to in paragraphs "f" and "g" must be certified by the technician responsible.~~ **~~(Revoked by Reso~~lution – RDC nº 208, of January 5, 2018)**

~~18.3. The agent duly registered with the respective CVPAF of clearance will be exempt from presenting the document in item "j".~~ **~~(Revoked by Resolution – RDC nº 208, of Januar~~y 5, 2018)**

~~19. The classification of goods or products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon import under sanitary approval.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

20. The import of samples of non-regularized medicines, without proof of safety and efficacy, intended for analysis for registration purposes, quality control tests, stability studies, bioequivalence and pharmaceutical equivalence or even testing of equipment participating in the manufacturing process or laboratory, whose composition includes active substances with proven safety and efficacy, must meet the sanitary requirements set out in this procedure, except for those relating to the presentation of the ANVISA registration.

SECTION V

PROCEDURE 2B- BIOLOGICAL PRODUCTS DERIVED FROM FLUIDS OR TISSUE OF ANIMAL ORIGIN AND ALLERGENS

21. The import of biological products derived from fluids or tissues of animal origin and allergens in the form of raw material, semi-finished product, bulk product or finished product, according to the classification of products available on the ANVISA website, will be subject to registration of Import Licensing at SISCOMEX, undergoing inspection by the health authority before customs clearance.

~~22. Mandatory documentation will be created for presentation to the authority sanitary facility where the input or product will be cleared:~~

22. The import process must be completed with the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **~~(Revoked by Resolution –~~ RDC nº 208, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **~~(Revo~~oked by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Declaration regarding the lots or items, identified alphanumerically, whatever fits;~~ **~~(R~~evoked by Resolution – RDC nº 208, of January 5, 2018)**

g) Analytical Quality Control Report active pharmaceutical ingredient and finished product, by batch or batch, issued by the manufacturer, except when dealing with imports of primary reference standards;

~~h) Power of attorney from the legal entity holding the regularization of the product with ANVISA to the legal representative, responsible for customs clearance;~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~i) Annotation document referring to proof of the docking of the good or product in the storage environment and its respective location, issued by the legal representative of the legal entity managing the customs area where the product is stored.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~22.1. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~22.2. The documents referred to in paragraphs "f" and "g" must be certified by the technician responsible.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~22.3. The agent will be exempt from presenting the document in item "h", duly registered with the respective clearance CVPAF.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~23. The classification of goods or products referred to in this Section is available on the ANVISA website, and produces legal effects for their classification upon import under sanitary approval.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

24. The import of samples of non-regularized medicines, without proof of safety and efficacy, intended for analysis for registration purposes, quality control tests, stability studies, bioequivalence and pharmaceutical equivalence or even testing of equipment participating in the manufacturing process or laboratory, whose composition includes active substances with proven safety and efficacy, must meet the sanitary requirements set out in this procedure, except for those relating to the presentation of the ANVISA registration.

SECTION VI

PROCEDURE 2C - BIOLOGICAL PRODUCTS OBTAINED BY BIOTECHNOLOGICAL PROCEDURES, MONOCLONAL ANTIBODIES, MEDICINES CONTAINING LIVE, ATTENUATED OR DEAD MICROORGANISMS AND PROBIOTI

~~25. The import of biological products obtained by biotechnological procedures, monoclonal antibodies, medicines containing live, attenuated or dead microorganisms and probiotics in the form of raw material, semi-finished product, bulk product or finished product, as per the framework of the~~

~~Products available on the ANVISA website will be subject to Import Licensing registration with SISCOMEX and favorable prior authorization for shipment, subject to inspection by the health authority before customs clearance.~~

25. The import of biological products obtained by biotechnological procedures, monoclonal antibodies, medicines containing live, attenuated or dead microorganisms and probiotics in the form of raw material, semi-finished product, bulk product or finished product, will be subject to Import Licensing registration at SISCOMEX, undergoing inspection by the health authority before customs clearance. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

~~25.1. Prior authorization for boarding will be given by ANVISA's technical sector at its headquarters in Brasília, DF.~~ **~~(Repealed by Resolution – DRC nº 208, of 5 de janeiro of 2018)~~**

~~25.2. It will be up to the interested company to submit a request for authorization to board abroad to the competent authority, by filling out a Petition for Authorization to Board Abroad.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~25.3. Mandatory documentation will be constituted for presentation to the area responsible for prior authorization for shipment of the input or product:~~ **~~(Revoked by Resolution – RDC nº 208, of~~ January 5, 2018)**

~~a) summarized product production protocol (in accordance with the WHO standard protocol, if the product is included therein);~~ **~~(Repealed by Resolution – DRC nº 208, of 5 de janeiro of 2018)~~**

~~b) certificate of quality control analysis of the raw material (active ingredient), issued by the manufacturer;~~ **~~(Revoked by Resolution~~ – RDC nº 208, of January 5, 2018)**

~~c) certificate of quality control analysis of the finished product, issued by the manufacturer~~; **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~d) product batch release certificate issued by the health authority of the country of origin;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~e) technical documents of the blood product used as a stabilizer, when as applicable~~: **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~e.1) declaration of origin of the plasma used;~~ **~~(Repealed by~~ Resolution – DRC nº 208, of 5 de janeiro of 2018)**

~~e.2) certificate of analysis of the quality control of the plasma used;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~e.3) certificate of release of the serology of the plasma used.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~26. Mandatory documentation will be created for presentation to the authority sanitary facility where the input or product will be cleared:~~

~~a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;~~

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when applicable~~;

~~d) Commercial Invoice - "Invoice";~~

~~e) Bill of Laden Cargo;~~

~~f) Declaration regarding the lots or items, identified alphanumerically, where applicable;~~

~~g) Analytical Quality Control Report of the finished product, by batch or batch, issued by the manufacturer, except when dealing with imports of primary reference standards;~~

~~h) Power of attorney instrument from the legal entity holding the regularization of the product with ANVISA to the legal representative, responsible for customs clearance;~~

~~i) Annotation document referring to proof of the docking of the good or product in the storage environment and its respective location, issued by the legal representative of the legal entity managing the customs area where the product is stored.~~

26. The import process must include the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II of this Resolution; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Commercial Invoice - “Invoice”; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

c) Bill of Laden Cargo; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

d) summary product production protocol (in accordance with the WHO standard protocol, if the product is included in it); **(Wording given by Resolution – DRC nº 208, of 5 de janeiro of 2018)**

e) certificate of analysis of the quality control of the raw material (active ingredient), issued by the manufacturer; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

f) certificate of quality control analysis of the finished product, issued by the manufacturer; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

g) product batch release certificate, issued by the health authority of the country of origin, when applicable; and **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

h) the following technical documents for the blood product used as a stabilizer, when applicable: declaration of origin of the plasma used; certificate of analysis of the quality control of the plasma used; and certificate of release of the serology of the plasma used. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

~~26.1. When the obligation of exclusive presentation in its original form is not specified, the documents referred to in this Chapter must be presented in their original form and copy, for authentication, or previously authenticated.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~26.2. The documents referred to in paragraphs "f" and "g" must be certified by the technician responsible.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~26.3. The agent duly registered with the respective CVPAF of clearance will be exempt from presenting the document in item "h".~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~27. The classification of goods or products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon importation under sanitary approval.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

28. The import of samples of non-regularized medicines, without proof of safety and efficacy, intended for analysis for registration purposes, quality control tests, stability studies, bioequivalence and pharmaceutical equivalence or even testing of equipment participating in the manufacturing process or

laboratory, whose composition includes active substances with proven safety and efficacy, must meet the sanitary requirements set out in this procedure, except for those relating to the presentation of the ANVISA registration.

~~SECTION VII~~

~~PROCEDURE 3 - PRODUCTS SUBJECT TO SPECIAL CONTROL REFERRED TO BY SVS/MS ORDINANCE No. 344 OF 1998 AND ITS UPDATES, IN ITS "C1" LISTS, "C2", "C3", "C4" E "C5"~~

SECTION VII

PROCEDURE 3 - PRODUCTS SUBJECT TO SPECIAL CONTROL REFERRED TO BY SVS/MS ORDINANCE No. 344 OF 1998 AND ITS UPDATES, IN ITS "C1" LISTS, "C2" E "C5"

(Wording given by Resolution – RDC nº 208, of January 5, 2018)

(The provisions applicable to List "C4", substances and antiretroviral medicines were repealed by Resolution – RDC nº 103, of August 31, 2016)

~~29. The import of products subject to the special control referred to in Ordinance SVS/MS nº 344, of 1998 and its updates, in the form of raw material, semi-finished product or finished product, according to the classification of products available on the website from ANVISA will be subject to Import Licensing registration with SISCOMEX and favorable prior authorization for shipment, subject to inspection by the health authority before customs clearance.~~

29. The import of products subject to the special control referred to in Ordinance SVS/MS nº 344, of May 12, 1998, and its updates, in the form of raw material, semi-finished product or finished product, will be subject to registration of Import Licensing at SISCOMEX, submitting to inspection by the health authority before customs clearance. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

~~30. Favorable prior authorization for boarding will be given upon manifestation by the competent technical area of ANVISA at its headquarters in Brasília, DF.~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~30.1. It will be up to the interested company to submit a request for authorization to board abroad to ANVISA, by filling out a Petition for Authorization to Board Abroad. (Revoked by Resolution – RDC nº 208, of January 5, 2018)~~

~~31. Mandatory documentation will be created for presentation to the health authority where the product will be released:~~

31. The import process must be completed with the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~d) Certificate of No Objection, or Declaration that this document is not issued in the country of origin;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

e) Commercial Invoice - "Invoice";

f) Bill of Laden Cargo;

~~g) Declaration regarding the lots or items, identified alpha-numerically, whatever fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

h) Analytical Quality Control Report, per batch or batch, issued by the manufacturer, except when dealing with imports of primary reference standards;

~~i) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~j) Power of attorney from the legal entity holding the regularization of the product with ANVISA to the legal representative, responsible for customs clearance;~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~l) Annotation document referring to proof of the product's docking in the storage environment and its respective location, issued by the legal representative of the legal entity managing the bonded area where the product is stored.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~31.1. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~31.2. The documents referred to in paragraphs "g" and "h" must be certified by the technician responsible, and, in that case, also by the person responsible or legal representative~~. **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~31.3. The agent duly registered with the respective CVPAF of clearance will be exempt from presenting the document in item "j".~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~32. The classification of products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon import under sanitary approval.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

SECTION VIII

PROCEDURE 4 - HEALTH PRODUCTS

(Requirement suspended regarding boarding authorization by Resolution - RDC nº 48, of August 31, 2012)

~~33. The import of health products in the form of raw material, semi-finished product, bulk product or finished product, according to the classification of products available on the ANVISA website, will be subject to Import Licensing registration with SISCOMEX and authorization favorable prior shipment, submitting to inspection by the health authority before customs clearance.~~

33. The import of health products, in the form of raw material, semi-finished product, bulk product or finished product, will be subject to Import Licensing registration with SISCOMEX, subject to inspection by the health authority before customs clearance. . **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

~~34. Prior authorization for shipment will be given upon a statement from the customs clearance health authority regarding the Import Licensing status.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~34.1. In the cases provided for in this Regulation, prior authorization for boarding will be given by means of a statement from the competent technical area of ANVISA at its headquarters in Brasília, DF.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~35. The interested company will be responsible for forwarding to the competent authority, in accordance with items 25 and 25.1 of this Section, a request for authorization to boa~~rd the

~~abroad, by filling out a Petition for Authorization to Board Abroad.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~35.1. Mandatory documentation will be constituted for presentation to the health authority when authorizing boarding abroad:~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~a) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~b) Declaration from the registration holder authorizing the import by a third party;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~c) Instrument of representation of the legal entity holding the regularization of the product with ANVISA in favor of the legal guardian or legal representative;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~d) information about the product and importing legal entity, such as product and company regularization and Import Licensing or Simplified Import Licensing number.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~35.2. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~35.3. The agent duly registered with the respective CVSPAF of customs clearance will be exempt from presenting the document in item "c".~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

35.4. You will be exempt from presenting information on regularizing the company to import raw materials from the product class in this Section.

~~36. Mandatory documentation will be created for presentation to the health authority where the product will be released:~~

~~a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;~~

~~b) Authorization of access for physical inspection, in accordance with tax legislation, when applicable~~;

~~c) Commercial Invoice - "Invoice";~~

~~d) Bill of Laden Cargo;~~

~~c) Declaration regarding the lots or items, identified alpha-numerically, where applicable;~~

~~f) Information, by batch or batch, issued by the manufacturer of each product;~~

~~g) Proof of product sterility or Quality Control Report for the batch, issued by the manufacturer, when applicable;~~

~~h) Power of attorney instrument from the legal entity holding the regularization of the product with ANVISA to the legal representative, responsible for customs clearance;~~

~~i) Annotation document referring to proof of the product's docking in the storage environment and its respective location, issued by the legal representative of the legal entity managing the bonded area where the product is stored.~~ ~~**(Requirement suspended by Resolution - RDC nº 48, of August 31, 2012)**~~

36. The import process must be completed with the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II of this Resolution; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

b) Commercial Invoice - “Invoice”; **(Wording given by Resolution – RDC nº 208, January 5, 2018)**

c) Bill of Laden Cargo; **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

d) Proof of product sterility, for sterile products; and **(Writing given by Resolution – RDC nº 208, of January 5, 2018)**

e) Declaration from the regularization holder authorizing import by third. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

~~36.1. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~36.2. The documents referred to in paragraphs "e", "f" and "g" must be certified by the technician responsible.~~ ~~**(Revoked by Resolution – RDC nº 208, of January 5, 2018)**~~

~~36.3. The agent duly registered with the respective CVPAF of clearance will be exempt from presenting the document in item "h".~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~37. The classification of the product referred to in this Section is available on the ANVISA website, and produces its legal effects for its classification upon import under sanitary approval.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

SECTION IX

PROCEDURE 5 - OTHER PRODUCTS

Subsection I

Procedure 5.1. - Foods

38. The import of food in the form of raw material, semi-finished product, bulk product or finished product, as per the classification of the products on the ANVISA website, will be subject to Import Licensing registration at SISCOMEX, submitting to the inspection by the health authority before customs clearance.

~~39. Mandatory documentation will be created for presentation to the authority where the product will be released:~~

39. The import process must be completed with the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Declaration regarding the lots or items, identified alphanumerically, whatever fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~g) Analytical Quality Control Report, per batch or batch, issued by the manufacturer or producer of products in accordance with the relevant health regulations;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~h) Certificate from "National Administration of Medicines, Foods and Technology", for products originating in Argentina, when applicable; (Revoked by~~

Resolution – RDC nº 208, of January 5, 2018)

i) Declaration from the registration holder authorizing the import by a third party;

j) Operating License, Permit or corresponding document relevant to the activity carried out (import, store, etc.) on the product in the national territory, issued by the competent health authority of the State, Municipality or District
Federal;

~~l) Instrument of representation of the legal entity holding the regularization of the product with ANVISA in favor of the legal guardian or legal representative;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~m) Annotation document referring to proof of the docking of the product in the storage environment and its respective location, issued by the legal representative of the legal entity managing the customs area where the product is stored. (Revoked by Resolution – RDC nº 208, of January 5, 2018)~~

~~39.1. The documents referred to in paragraphs "f" and "g" must be certified by the person responsible or legal representative; (Revoked by Resolution – RDC nº 208, of January 5, 2018)~~

~~39.2. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~39.3. The agent duly registered with the respective CVPAF of customs clearance will be exempt from presenting the document in item "l". (Revoked by Resolution – RDC nº 208, of January 5, 2018)~~

~~40. The classification of products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon import under sanitary approval. (Revoked by Resolution – RDC nº 208, of January 5, 2018)~~

Subsection II

Procedure 5.2. - Cosmetics, Hygiene Products and Perfumes

41. The import of cosmetics, hygiene products and perfumes in the form of raw material, semi-finished product, bulk product or finished product, according to the classification of products available on the ANVISA website, will be subject to Import Licensing registration at SISCOMEX, subjecting itself to inspection by the health authority prior to customs clearance.

~~42. Mandatory documentation will be created for presentation to the health authority where the product will be released:~~

42. The import process must be completed with the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **~~(Revoked by Resolution – RDC nº 208~~, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **~~(Revoke~~d by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Information about the product and importing legal entity, such as product and company regularization and Import Licensing or Simplified Import Licensing number.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~g) Declaration regarding the lots or items, identified alphanumerically, in the whatever fits;~~ **~~(~~Revoked by Resolution – RDC nº 208, of January 5, 2018)**

h) Declaration from the registration holder authorizing the import by a third party;

~~i) Instrument of representation of the legal entity holding the regularization of the product with ANVISA in favor of the legal guardian or legal representative;~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~j) Annotation document referring to proof of the product's docking in the storage environment and its respective location, issued by the legal representative of the legal entity managing the bonded area where the product~~

~~is stored.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~42.1. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~42.2. The document referred to in paragraph "g" must be certified by the technician responsible.~~

~~(Revoked by Resolution~~ – RDC nº 208, of January 5, 2018)

~~42.3. The agent duly registered with the respective CVPAF of customs clearance will be exempt from presenting the document in item "i".~~ **~~(Revoked by Resolution – RDC nº 208, of January~~ 5, 2018)**

~~43. The classification of products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon import under sanitary approval.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

Subsection III

Procedure 5.3. - Medicines

44. The import of medicines in general, not covered by the previous provisions, in the form of raw material, semi-finished product, bulk product or finished product, according to the classification of products available on the ANVISA website, will be subject to Licensing registration of Importation at SISCOMEX, undergoing inspection by the health authority before customs clearance.

~~45. Mandatory documentation will be created for presentation to the health authority where the product will be released:~~

45. The import process must be completed with the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **~~(Revoked by Resolution – RDC nº 208~~, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **~~(Revoke~~d by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Declaration regarding the lots or items, identified alphanumerically, whatever fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

g) Analytical Quality Control Report, per batch or batch, issued by the manufacturer, except when dealing with imports of primary reference standards;

~~h) Information about the product and importing legal entity, such as product and company regularization and Import Licensing or Simplified Import Licensing number.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

i) Declaration from the registration holder authorizing the import by a third party;

~~j) Instrument of representation of the legal entity holding the regularization of the product with ANVISA in favor of the legal guardian or legal representative;~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~l) Annotation document referring to proof of the product's docking in the storage environment and its respective location, issued by the legal representative of the legal entity managing the customs area where the product is stored.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~45.1. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~45.2. The documents referred to in paragraphs "f" and "g" must be certified by the technician responsible.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~45.3. The agent duly registered with the respective CVPAF of clearance will be exempt from presenting the document in item "j".~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~46. The classification of products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon import under sanitary approval.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

47. The import of samples of non-regularized medicines, without proof of safety and efficacy, intended for analysis for registration purposes, quality control tests, stability studies, bioequivalence and pharmaceutical equivalence or even tests of equipment participating in the manufacturing process or laboratory, whose composition includes active substances with proven safety and efficacy, must meet the sanitary requirements set out in this procedure, except for those relating to the presentation of the ANVISA registration.

Subsection IV

Procedure 5.4. – Sanitizing

48. The import of sanitizing products in the form of raw material, semi-finished product, bulk product or finished product, according to the classification of products available on the ANVISA website, will be subject to Import Licensing registration at SISCOMEX, subject to the inspection by the health authority before customs clearance.

~~49. Mandatory documentation will be created for presentation to the health authority where the product will be released:~~

49. The import process must be completed with the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **~~(Revoked by Resolution – RDC nº 208~~, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **~~(Revoke~~d by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Declaration regarding the lots or items, identified alphanumerically, in the whatever fits;~~ **~~(~~Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~g) Information about the product, its respective batch and shipment, and importing legal entity, such as product and company regularization and registration number Import Licensing or Simplified Import Licensing;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

h) Declaration from the registration holder authorizing the import by a third party;

~~i) Instrument of representation of the legal entity holding the regularization of the product with ANVISA in favor of the legal guardian or legal representative;~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~j) Annotation document referring to proof of the product's docking in the storage environment and its respective location, issued by the legal representative of the legal entity managing the bonded area where the product is stored.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~49.1. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~

(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~49.2. The document referred to in paragraph "f" must be certified by the technician responsible.~~

~~(Revoked by Resolution~~ – RDC nº 208, of January 5, 2018)

~~49.3. The agent duly registered with the respective CVPAF of customs clearance will be exempt from presenting the document in item "i".~~ **~~(Revoked by Resolution – RDC nº 208, of J~~anuary 5, 2018)**

49.4. The import of raw materials belonging to the sanitizing class of this Section will be exempt from the presentation of company regularization information, without exempting the presentation of the Operating License, Permit or corresponding document pertinent to the storage of the product in the national territory, issued by the health authority. competent authority of the State, Municipality or Federal District, in accordance with local regulations for concession and renewal.

~~50. The classification of products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon import under sanitary approval.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

Subsection V

Procedure 5.5. - Products for In Vitro Diagnostics

51. The import of diagnostic products, according to the product classification available on the ANVISA website, will be subject to Import Licensing registration with SISCOMEX, subject to inspection by the health authority before customs clearance.

~~52. Mandatory documentation will be created for presentation to the health authority where the product will be released:~~

52. The import process must be completed with the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **~~(Revoked by Resolution – RDC nº 208~~, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **~~(Revoke~~d by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Declaration regarding the lots or items, identified alphanumerically, whatever fits;~~ **~~(Rev~~oked by Resolution – RDC nº 208, of January 5, 2018)**

~~g) Information about the product, its respective batch and batch;~~ **~~(Revoked by~~ Resolution – RDC nº 208, of January 5, 2018)**

h) Proof of product sterility, issued by the manufacturer, when applicable;

i) Declaration from the registration holder authorizing the import by a third party;

~~j) Instrument of representation of the legal entity holding the regularization of the product with ANVISA in favor of the legal guardian or legal representative;~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~l) Annotation document referring to proof of the product's docking in the storage environment and its respective location, issued by the legal representative of the legal entity managing the bonded area where the product is stored.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~52.1. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~52.2. The document referred to in paragraph "f" must be certified by the technician responsible.~~ **~~(Revoked by Resolution~~ – RDC nº 208, of January 5, 2018)**

~~52.3. The agent duly registered with the respective CVPAF of clearance will be exempt from presenting the document in item "j".~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~53. The classification of products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon import under sanitary approval.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

Subsection VI

Procedure 5.6. - Miscellaneous Products

54. The import of products, in accordance with this Section, according to the product classification available on the ANVISA website, will be subject to Import Licensing registration with SISCOMEX, subject to inspection by the health authority before customs clearance.

54.1. Products covered by this Section are:

~~a) hair in its various forms of presentation for human use;~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~b) wigs, beards, eyebrows, eyelashes, locks and similar articles for human use;~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~c) wool, hair and other textile materials, prepared for the manufacture of wigs or similar articles for human use;~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

d) bottle, bottle nipple, pacifier, teether;

~~e) clothing and accessories for medical, dental or hospital use, including manufactured articles and clothing patterns;~~ **~~(Revoked by~~**
Resolution – RDC nº 208, of January 5, 2018)

~~f) textile artifacts, footwear, hats and artifacts of similar use, used in cases of donation.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~55. Mandatory documentation will be created for presentation to the authority sanitary area where the product will be untangled~~

55. The import process must be completed with the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Information about the product, its respective batch and batch, when applicable;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~g) Declaration from the registration holder authorizing the import by a third party, when it fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~h) Instrument of representation of the legal entity holding the regularization of the product with ANVISA in favor of the legal guardian or legal representative;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~i) Annotation document referring to proof of the product's docking in the storage environment and its respective location, issued by the legal representative of the legal entity managing the bonded area where the product is stored.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~55.1. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~55.2. The agent duly registered with the respective CVPAF of clearance will be exempt from presenting the document in item "h".~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~56. The classification of products covered by this Section is available on the ANVISA website, and produces its legal effects for their classification upon import under sanitary approval.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

SECTION X

PROCEDURE 6 - GOODS AND PRODUCTS CONTAINING FABRICS OR FLUIDS RUMINANT ANIMALS

~~57. The import of raw material, semi-finished product, bulk product or finished product, of any product class, according to the classification of products available on the ANVISA website, will be subject to Import Licensing registration with SISCOMEX and prior authorization favorable for boarding, submitting to inspection by the health authority before customs clearance.~~

57. The import of raw material, semi-finished product, bulk product or finished product, of any product class, according to the classification of products available on the ANVISA Portal, will be subject to Import Licensing registration at SISCOMEX, submitting it subject to inspection by the health authority prior to customs clearance. **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

~~58. Prior authorization for boarding will be given upon approval from the customs clearance health authority.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~58.1. In the cases provided for in this Regulation, prior authorization for boarding will be given through a statement from the ANVISA technical sector at its headquarters, in Brasília, DF.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~58.2. The interested company will be responsible for forwarding to the competent authority, in accordance with items 58 and subitem 58.1 of this Section, a request for authorization to board abroad, by filling out a Petition for Authorization to Board Abroad.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~59. Mandatory documentation will be created for presentation to the health authority where the product will be released:~~

59. The import process must be completed with the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Information about the product, its date of manufacture, its respective batch and departure, issued by the manufacturer, importing legal entity, regularization of the product and the company and Import Licensing or Licensing number Simplified Import;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~g) Declaration regarding the lots or items, identified alpha-numerically, whatever fits;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~h) Proof of sterility of the product, issued by the manufacturer, when fit;~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

i) Declaration from the registration holder authorizing the import by a third party;

~~j) Power of attorney from the legal entity holding the regularization of the product with ANVISA to the legal representative, responsible for customs clearance;~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~l) Annotation document referring to proof of the product's docking in the storage environment and its respective location, issued by the legal representative of the legal entity managing the bonded area where the product is stored.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~59.1. When the obligation for exclusive presentation in its original form is not specified, the documents referred to in this Section must be presented in their original form and copy, for authentication, or previously authenticated.~~
(Revoked by Resolution – RDC nº 208, of January 5, 2018)

~~59.2. The documents referred to in paragraphs "f", "g" and "h" must be certified by the technician responsible.~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~59.3. The agent duly registered with the respective CVSPAF of customs clearance will be exempt from presenting the document in item "j".~~ **(Revoked by Resolution – RDC nº 208, of January 5, 2018)**

~~60. The classification of products referred to in this Section is available on the ANVISA website, and produces legal effects for their classification in the~~

~~import under sanitary approval.~~ **~~(Revo~~ked by Resolution – RDC nº 208, of January 5, 2018)**

SECTION XI

PROCEDURE 7 - GOODS AND PRODUCTS UNDER INTERVENTION RESULTING FROM INTERNATIONAL EPIDEMIOLOGICAL CONTEXT, EMERGENCY AND TEMPORARY

62. The import of products in the form of raw material, semi-finished product, bulk product or finished product, as defined by act of the Director responsible for ANVISA in situations of emergency or temporary international epidemiological context, according to the classification of products available in the ANVISA website, will be subject to Import Licensing registration with SISCOMEX and favorable prior authorization for shipment, subject to inspection by the health authority before customs clearance.

63. Prior authorization for boarding will be given upon approval from the customs clearance health authority.

63.1. In the cases provided for in this Regulation or defined by act of the Director responsible for ANVISA, prior authorization for boarding will be given through a statement from the ANVISA technical sector at its headquarters, in Brasília, DF.

64. The interested company will be responsible for forwarding to the competent authority, in accordance with items 63 and 63.1 of this Section, a request for authorization to board abroad, by filling out a Petition for Authorization to Board Abroad.

~~65. Mandatory documentation will be created for presentation to the health authority where the product will be released:~~

65. The import process must include the following documents: **(Wording given by Resolution – RDC nº 208, of January 5, 2018)**

a) Petition for Inspection and Health Release referred to in subsection 1.2. of Chapter II;

~~b) Union Collection Guide - GRU, from the National Treasury Secretariat, as provided for in the relevant health legislation;~~ **~~(Revoked by Resolu~~tion – RDC nº 208, of January 5, 2018)**

~~c) Authorization of access for physical inspection, in accordance with tax legislation, when it fits;~~ **~~(Rev~~oked by Resolution – RDC nº 208, of January 5, 2018)**

d) Commercial Invoice - "Invoice";

e) Bill of Laden Cargo;

~~f) Declaration regarding the lots or items, identified alphanumerically, whatever fits;~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

g) Information about the product, its date of manufacture, its respective batch and departure, issued by the manufacturer, importing legal entity, regularization of the product and the company and Import Licensing or Licensing number
Simplified Import;

h) Proof of product sterility or Quality Control Report for the batch, issued by the manufacturer, when applicable;

i) Declaration from the registration holder authorizing the import by a third party;

~~j) Power of attorney from the legal entity holding the regularization of the product with ANVISA to the legal representative, responsible for customs clearance;~~
~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~

~~l) Annotation document referring to proof of the product's docking in the storage environment and its respective location, issued by the legal representative of the legal entity managing the bonded area where the product is stored.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~65.1. When the obligation of exclusive presentation in its original form is not specified, the documents referred to in this Chapter must be presented in their original form and copy, for authentication, or previously authenticated.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

~~65.2. The documents referred to in paragraphs "f", "g" and "h" must be certified by the technically responsible and/or legally responsible person.~~ **~~(Revoked by Resolution –~~ RDC nº 208, of January 5, 2018)**

~~65.3. The agent duly registered with the respective CVSPAF of customs clearance will be exempt from presenting the document in item "j".~~ **~~(Revoked by Resolution – RDC nº 208, of Ja~~nuary 5, 2018)**

~~66. The classification of products referred to in this Section, defined by the act of the Director responsible for ANVISA, will be available on ANVISA's website, and will produce legal effects for their classification upon import under sanitary approval.~~ **~~(Revoked by Resolution – RDC nº 208, of January 5, 2018)~~**

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

CHAPTER XL

QUADRO I

IMPORT PURPOSES

Fairs and events:

EXHIBITION AT FAIRS AND EVENTS.

EXHIBITION WITH DEMONSTRATION AT FAIRS AND EVENTS.

EXHIBITION, DEMONTRATION AND DISTRIBUTION AT FAIRS AND EVENTS.

Clinical research:

CLINICAL RESEARCH:

CLINICAL RESEARCH / MONITORING AND/OR EVALUATION (Medical products and in vitro diagnostic products).

CLINICAL RESEARCH / COLLECTION (KIT) OF BIOLOGICAL MATERIAL LINKED TO MONITORING AND/OR EVALUATION.

International Donation:

EXCLUSIVE INTERNATIONAL DONATION OF USED GARMENTS AND USED TEXTILE AND SYNTHETIC ARTIFACTS.

INTERNATIONAL DONATION OF PRODUCTS UNDER HEALTH SURVEILLANCE - MISCELLANEOUS.

Free Store

FREE STORE, TRADE AND STORAGE;

Quality control:

QUALITY CONTROL TESTING;

Product Registration Approval:

APPROVAL OF REGISTRATION OR REGULARIZATION OF THE PRODUCT WITH THE SNVS.

Equipment Tests:

OPERATIONAL TESTING ON INDUSTRIAL OR LABORATORY EQUIPMENT.

Bioavailability, bioequivalence or pharmaceutical equivalence test:

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

BIOAVAILABILITY, BIOEQUIVALENCE OR PHARMACEUTICAL EQUIVALENCE TEST.

Market research:

MARKET RESEARCH.

Labeling or packaging assessment:

EVALUATION OF PACKAGING OR LABELING.

Safety and Effectiveness:

TEST TO VERIFY SAFETY AND EFFECTIVENESS IN COSMETICS, PERFUMES AND PERSONAL HYGIENE PRODUCTS.

Clinical laboratory diagnosis:

CLINICAL LABORATORY DIAGNOSIS OF HUMAN BIOLOGICAL MATERIAL.

CLINICAL LABORATORY DIAGNOSIS OF HUMAN BIOLOGICAL MATERIAL LINKED TO CLINICAL RESEARCH UNDER DEVELOPMENT ABROAD.

REFERENCE MATERIAL ORIGINATING FROM HUMAN BIOLOGICAL MATERIAL INTENDED FOR CLINICAL LABORATORY DIAGNOSIS.

DEVELOPMENT OR VALIDATION OF ANALYTICAL METHODOLOGY IN CLINICAL DIAGNOSTIC LABORATORY OF HUMAN BIOLOGICAL MATERIAL.

Individual, personal consumption:

INDIVIDUAL, INDIVIDUAL USE, NOT CHARACTERIZED AS COMMERCE AND RESALE, OR USE IN THIRD PARTIES.

Individual, provision of services to third parties:

INDIVIDUAL TO PROVIDE SERVICES TO THIRD PARTIES.

Human Cells and Tissues:

SKIN, MUSCULOSKELETAL TISSUE AND HEART VALVES FOR PURPOSES THERAPEUTICS;

HEMATOPOETIC PROGENITOR CELLS FOR THERAPEUTIC PURPOSES;

GERMINATIVE CELLS AND TISSUE AND HUMAN PRE-EMBRYOS FOR THERAPEUTIC PURPOSES.

HUMAN CORNEAS FOR THERAPEUTIC PURPOSES;

Infirmaries, pharmacies or on-board medical suite:

REPLACEMENT OR INITIAL SUPPLY OF NURSE, PHARMACY OR MEDICAL SET ON BOARD TRANSPORTATION; BRAZILIAN OR FOREIGNERS UNDER CHARTER OR LEASE.

REPLACEMENT OR INITIAL SUPPLY OF NURSE, PHARMACY OR ON-BOARD MEDICAL SET FOR FOREIGN TRANSPORTATION MEANS.

Import licensing from another institution:

DEFERRED LICENSING FOR THE IMPORT OF PRODUCTS FOR THE PURPOSE OF USE WHICH CONTROL IS PROVIDED BY ANOTHER CONSENTING INSTITUTION.

Return of Exported Product:

RETURN OF EXPORTED GOODS OR PRODUCTS UNDER HEALTH SURVEILLANCE.

RETURN TO THE COUNTRY OF GOODS OR PRODUCTS UNDER HEALTH SURVEILLANCE EXPORTED FOR REPAIRS, REPAIRS OR RESTORATION ABROAD.

Return to Abroad of Imported Product:

REJECTION OR RETURN ABROAD OF GOODS OR PRODUCTS WITH SUSPECTED HEALTH IRREGULARITY OR CONFIRMED IRREGULARITY LABORATORIALLY.

Industry or commerce:

INSPECTION AND SANITARY CLEARANCE OF IMPORTED GOODS OR PRODUCTS FOR INDUSTRY OR COMMERCIAL PURPOSES.

Product unbanning:

SANITARY DISINTERDICTION OF GOODS OR PRODUCTS.

Release of Custody Term:

RELEASE OF CUSTOMER AND RESPONSIBILITY TERM.

Term of Disposal:

ISSUE OF A TERMS OF USE OF PRODUCTS UNDER HEALTH SURVEILLANCE.

Standard or Reference Material:

Ministry of Health - MS

National Health Surveillance Agency - ANVISA

STANDARD OR REFERENCE MATERIAL FOR QUALITATIVE CONTROL OF RAW MATERIALS OR PRODUCTS UNDER SANITARY SURVEILLANCE.

Public health programs:

EXCLUSIVE USE IN PUBLIC HEALTH PROGRAMS - ACQUISITION BY INTERNATIONAL MULTILATERAL ORGANIZATION.

EXCLUSIVE USE IN PUBLIC HEALTH PROGRAMS - ACQUISITION BY MINISTRY OF HEALTH OR ITS RELATED ENTITIES.

TABLE 2

NATURE OF THE GOOD OR PRODUCT

FINISHED PRODUCT.

BULK PRODUCT WITHOUT PRIMARY PACKAGING.

BULK PRODUCT WITH PRIMARY PACKAGING.

SEMI-MADE PRODUCT.

RAW MATERIAL OR INPUTS.

REFERENCE STANDARD

(*) Republished because it appeared in DOU nº 216, of 11/6/2008, Section 1, Page 36, with an error in the original.