Form with Declaration of compliance with the requirements for the admissibility of the optimized regulatory trust analysis procedure (*Reliance*), in accordance with RDC No. 945/2024 and IN No. 338/2024.

1) Petitions subject to analysis by the optimized procedure

I. (__) Approval in the Process of the Clinical Development Dossier of Medication (DDCM), File No. _____ (*inform the DDCM file number*).

II. (__) Approval in Clinical Research Process (DEEC), File number _____ (*inform the DEEC file number*).

III. (__) Substantial modification to the product under investigation, File No. _____ (*inform the file number of the modification request*).

IV. (__) Substantial amendment to the Clinical Protocol, File No. _____ (*enter the file number of the amendment petition*).

2) AREEs and documents subject to the optimized analysis procedure

In compliance with what is described in Art. 42 of RDC nº 945/2024 and Art. 5th of IN nº 338/2024, **I DECLARE** that:

a) The Active Pharmaceutical Ingredient (API) Dossier _____ [*provide the name or code of the API*] and the Investigational Product (DPI) or IMPD, version _____ [*provide the version*] linked to the DDCM petition informed in "subparagraph I", of "item 1" or in the petition for Substantial Modification to the product under investigation informed in "subparagraph III", of "item 1", referring to the investigational drug _____ [*provide the name/code of the drug*], was approved by the Equivalent Foreign Regulatory Authority (AREE) _____ [*provide the name of the AREE*] of _____ [*provide the name of the country*].

b) The manufacturing process of the API and the investigational product approved by AREE complied with the guidelines and principles described in the current ICH_____ guides [*inform the number of the guides, when applicable*], according to the clinical development phase.

c) The clinical protocol, code/version _____ [*inform the code and version*] linked to the DEEC petition informed in "inciso II", of "item 1" or in the petition for amendment to the clinical protocol informed in "inciso IV", of "item 1" was approved by the Equivalent Foreign Regulatory Authority (AREE) _____ [*inform the name of the AREE*] of _____ [*inform the name of the country*].

I assume full civil and criminal responsibility for the information provided here.

_____ _____

Legal Representative of the Sponsor Technical manager