



**Ministry of Health - MS**  
**National Health Surveillance Agency - ANVISA**

**COLLEGIATE BOARD RESOLUTION - RDC No. 763, OF NOVEMBER 25, 2022 (\*)**

**(Published in DOU No. 225, of December 1, 2022)**

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Amends the Resolution of the Collegiate Board - RDC No. 205, of December 28, 2017.

The **Collegiate Board of the National Health Surveillance Agency**, in the use of the attributions conferred by art. 15, III and IV, combined with art. 7, III and IV of Law No. 9,782, of January 26, 1999, and art. 187, VI, § 1 of the Internal Regulation approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, resolves to adopt the following Resolution, as resolved at a meeting held on November 23, 2022, and I, Director- President, I order its publication.

Art. 1st The Resolution of the Collegiate Board of Directors - RDC No. 205, of December 28, 2017, becomes effective with the following changes:

"Art. 10.....

I - request for a pre-submission meeting, if the interested party deems it necessary, for the presentation of the DDCM, specific clinical trial dossier or substantial modification due to protocol inclusion;

II - holding a pre-submission meeting, if the interested party deems it necessary, for the presentation of the DDCM, specific clinical trial dossier or substantial modification by inclusion of the protocol, within sixty days after the request by the interested party;

.....(NR)

Art. 2 This Resolution comes into force from December 1, 2022.

**ANTONIO BARRA TORRES**  
**CEO**

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**(\*) (CODOU No.) Republished because it was published in the DOU on 12/1/2022, Section 1, page 120, with an error.**