

COLLEGIATE BOARD RESOLUTION – RDC No. 763 OF 25 NOVEMBER 2022

Amends Collegiate Board Resolution
– RDC No. 205 of 28 December 2017.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, items III and IV, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VI, Paragraph 1 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 23 November 2022, and I, Director-President, determine its publication.

Article 1. Collegiate Board Resolution – RDC No. 205 of 28 December 2017 shall come into effect with the following alterations:

"Article 10.....

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

II – hold a pre-submission meeting, if the interested party deems it necessary, for the submission of a DDCM, a specific clinical trial dossier, or a substantial modification due to protocol inclusion, within sixty days after the interested party's request;

....."(new wording)

Article 2. This Resolution shall come into effect on 1 December 2022.

ANTONIO BARRA TORRES

Director-President