

COLLEGIATE BOARD RESOLUTION – RDC NO. 850 OF 20 MARCH 2024

(Published in the Federal Official Gazette no. 57 of 22 March 2024)

Alters Collegiate Board Resolution – RDC no. 497 of 20 May 2021, which provides for the administrative procedures to grant the Good Manufacturing Practices Certificate and the Good Distribution and/ or Storage Practices Certificate.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, and Article 7, items III and IV of Law no. 9,782 of 26 January 1999, and item VI, paragraph 1 of Article 187 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Resolution, as decided upon in a meeting held on 19 March 2024, and I, Director-President, determine its publication.

Article 1. Collegiate Board Resolution – RDC no. 497 of 20 May 2021, published in the Federal Official Gazette no. 98 of 26 May 2021, Section 1, page 205, shall be effective with the following writing:

“Article 8.

Paragraph 1. The Good Manufacturing Practices Certificate for manufacturers of medical devices granted through the Medical Device Single Audit Program (MDSAP) shall be valid for four years.

Paragraph 2. The validity established in Paragraph 1 is conditioned upon the manufacturer’s permanence in the Medical Device Single Audit Program (MDSAP) during the whole validity period of the certificate. (New writing)

Paragraph 3. The requests for Good Manufacturing Practices Certificate by medical device manufacturers granted through the Medical Device Single Audit Program (MDSAP), as well as their renewals protocolled before Collegiate Board Resolution – RDC no. 850 of 20 March 2024 enters into force, the decision on which has not yet been published in the Federal Official Gazette, shall be valid for four years.” (New writing)

Article 2. This Resolution shall enter into force on 1 April 2024.

ANTONIO BARRA TORRES
Director-President