MINISTRY OF HEALTH

NATIONAL HEALTH SURVEILLANCE AGENCY

BOARD

RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS - RDC NO. 850, OF MARCH 20, 2024

Amends the Resolution of the Collegiate Board of Directors - RDC No. 497, of May 20, 2021 , which provides for the administrative procedures for granting Certification of Good Manufacturing Practices and Certification of Good Distribution and/or Storage Practices.

THE COLLEGIATE BOARD OF DIRECTORS OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the exercise of the powers conferred on it by article 15, III and IV , together with article 7, III and IV of Law No. 9,782, of January 26, 1999 , and article 187, VI, paragraph 1 of the Internal Regulations 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 March 19, 2024, and I, Chief Executive Officer, hereby order its publication

Art. 1 The Resolution of the Collegiate Board of Directors - RDC No. 497, of May 20, 2021 , published in the Federal Official Gazette No. 98, of May 26, 2021, Section 1, page 205, is now in force with the following wording:

" Article 8 .....

Paragraph 1 - The validity of the Certification of Good Manufacturing Practices of medical device manufacturers granted through the Single Audit Program in Medical Devices (MDSAP) is four years.

Paragraph 2 - The validity established in paragraph 1 is conditioned to the permanence of the manufacturer in the Single Audit Program in Medical Devices (MDSAP) during the entire period of validity of the certificate.' (NR)

Paragraph 3 - Petitions for Certification of Good Manufacturing Practices of medical device manufacturers granted through the Single Audit Program in Medical Devices (MDSAP) and their renewals filed before the entry into force of the Resolution of the Collegiate Board of Directors - RDC No. 850, of March 20, 2024 , whose decision has not been published in the Federal Official Gazette, will be valid for four years." (NR)

Art. 2 This Resolution enters into force on April 1, 2024.

ANTONIO BARRA TORRES
Chief Executive Officer

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This text does not replace the Official Publication.