MINISTRY OF HEALTH

NATIONAL HEALTH SURVEILLANCE AGENCY

BOARD

RESOLUTION RDC NO. 542, OF AUGUST 30, 2021

Defines "group of products" to which item 5.3 of Annex II of Law 9.782 of January 26, 1999 applies.

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The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the powers conferred on it by arts. 7, item III, and 15, items III and IV, of Law No. 9,782, of January 26, 1999, and considering the provisions of article 53, item VI and §§ 1 and 3, of the Internal Regulations, approved by the Resolution of the Collegiate Board of Directors - RDC No. 255, of December 10, 2018, resolves to adopt the following Collegiate Board Resolution, as resolved at a meeting held on August 30, 2021, and I, Chief Executive Officer, hereby order its publication.

Art. 1 This Resolution defines "group of products" to which item 5.3 of Annex II of Law 9.782 of January 26, 1999 applies.

Art. 2 The "group of products" to which item 5.3 of Annex II of Law No. 9,782 of 1999 applies, is understood to be the "family of medical devices" of the same manufacturer, where each product that constitutes it contains the following similar characteristics:

I - technology of the product, including the fundamentals of its operation and action, its content or composition, performance, as well as the accessories that integrate it;

II - indication, purpose or use for which the product is intended, as indicated by the manufacturer; and

III - precautions, restrictions, warnings, special care and instructions on storage and transportation of the product.

Sole Paragraph. The medical devices referred to in this article are the products defined as "related" in Law No. 6,360, of September 23, 1976 and in Decree 8,077, of August 14, 2013.

Article 3 - The manufacturer or importer of medical devices may request the registration, exemption and change of the family registration of these products, detailing the similarities and comparative differences in the characteristics between each product model that constitutes the family.

Article 4 - The National Health Surveillance Agency shall evaluate the characteristics of the medical devices described in Article 2 of this Resolution and shall indicate their corresponding families.

Article 5 The Resolution of the Collegiate Board of Directors - RDC No. 97, of November 9, 2000, published in the Federal Official Gazette No. 217-E, of November 10, 2000, is hereby revoked.

Art. 6 This Resolution enters into force on October 1, 2021.

ANTONIO BARRA TORRES

D.O.U., 08/31/2021 - Section 1

This text does not replace the Official Publication.