

**RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS –
RDC No. 211, OF JANUARY 22, 2018**

It provides for the validity period of the registration of medical devices.

The Collegiate Board of the National Health Surveillance Agency, in the use of the attribution conferred on it by article 15, III and IV allied to article 7, III, and IV, of Law No. 9,782, of January 26, 1999, article 53, V, §§ 1 and 3 of the Internal Regulations approved pursuant to Annex I of the Resolution of the Collegiate Board of Directors – RDC No. 61, of February 3, 2016, resolves to adopt the following Resolution of the Board of Executive Officers, as resolved at a meeting held on January 16, 2018, and I, the Chief Executive Officer, determine its publication.

Art. 1 The period of 10 (ten) years is established for the validity of the registration of medical devices.

Art. 2 This Resolution applies to medical devices within the scope of "correlated" referenced by Law No. 6,360, of September 23, 1976.

Single paragraph. Medical devices cover medical products and in vitro diagnostic products, as defined in the Collegiate Board Resolution

– RDC No. 185, of October 22, 2001, and in the Resolution of the Collegiate Board of Directors – RDC No. 36, of August 26, 2015.

Art. 3 Item 13 of Part 3 of the Annex to the Resolution of the Collegiate Board of Directors - RDC No. 185, of 2001, shall enter into force with the following wording:

ANNEX

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PART 3 - Procedures for Registration

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13. The registration of health products will be valid for 10 (ten) years, counted from the day of its publication in the Official Gazette of the Union, and may be revalidated successively for the same period." (NR)

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Art. 4 The validity periods of the registrations granted prior to the publication of this Resolution are automatically extended to 10 (ten) years.

Art. 5 Petitions for revalidation of medical device registration filed up to the date of publication of this Resolution shall be closed.

Article 6 This Resolution shall enter into force on the date of its publication.

JARBAS BARBOSA DA SILVA JR.