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Solution

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COLLEGIATE BOARD RESOLUTION - RDC No. 340, OF MARCH 6, 2020

It provides for changes in information in the processes of regularization of medical devices and provides other measures.

The Collegiate Board of the National Health Surveillance Agency, in the use of the attributions 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 53, V, §§ 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 Resolution, as resolved at a meeting held on March 3, 2020, and I, the Substitute Chief Executive Officer, determine its publication.

CHAPTER I
OF THE INITIAL PROVISIONS

Goal

Art. 1 This Resolution aims to classify and establish the procedures for the changes of information in the processes of regularization of medical devices.

Single paragraph. For the purposes of this Resolution, medical devices are considered to be medical devices and in vitro diagnostic products regulated by Collegiate Board Resolution - RDC No. 185, of October 22, 2001, Collegiate Board Resolution - RDC No. 36, of August 26, 2015, and Collegiate Board Resolution - RDC No. 40, of August 26, 2015, or later regulations.

Section I
Scope

Art. 2 This Resolution applies to changes in the processes of regularization of medical devices.

Section II
Definitions

Art. 3 For the purpose of this Resolution, the following definitions are adopted:

I. amendment: modification of information submitted to ANVISA in the process of regularization of the medical device and in their respective secondary petitions;

II. change of approval required: change of greater sanitary relevance, which deals with a change to be introduced in the regularization process, being authorized in national territory only after technical documentary analysis and favorable manifestation of ANVISA;

III. change of immediate implementation: change of medium sanitary relevance, which deals with a change to be introduced in the regularization process, and its implementation is authorized in the national territory after the filing of a petition with ANVISA; and

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IV. non-reportable change: any other change of minor health relevance, resulting from a change that is not classified as required approval or immediate implementation, and that does not depend on ANVISA's protocol for implementation.

CHAPTER II
CLASSIFICATION OF AMENDMENTS AND GENERAL REQUIREMENTS

Art. 4 The changes of information presented in the process of regularization of medical devices are classified in:

I. change of approval required;
II. change of immediate implementation; and
III. non-reportable change.

§ 1° The petition for the amendments contained in items I and II of this article shall comply with the provisions of the Normative Instruction that details the petitioning matters applicable to this Resolution.

§ 2 For the purposes of this Resolution, any changes of minor relevance that are not classified as required approval or immediate implementation are classified as non-reportable changes, as well as: changes in information that do not modify the design of the medical device; bug fixes in software; non-technical changes such as images, formatting, layouts, symbols and text adaptations of documents without adding risk; updates to Authorization information Company Operation; contact changes (e.g. telephones or postal address), technical assistance and website.

§ 3 The changes listed in § 2 shall be controlled by the quality system of the holder of the regularization and be incorporated in subsequent petitions.

§ 4 The petition for amendment to medical devices of risk class I shall be executed by the regime of immediate implementation, except in the case of non-reportable change.

Art. 5 The petition for change of information must be accompanied by the supporting documentation of the modification to be implemented, in compliance with the current health legislation.

Art. 6 The change of immediate implementation that has interdependence with the change of approval required shall be petitioned together with this, incorporating its contents.

Single paragraph. In the event of the caput of this article, ANVISA will simultaneously analyze the requested changes, applying to the modification classified as immediate implementation the effects provided for in the final part of item III, of article 3 of this Resolution.

Art. 7 The changes resulting from field action notified to ANVISA in order to ensure the safety and effectiveness of the device in relation to the user and the patient will have their analyses prioritized.

Single paragraph. To request the prioritization of analysis cited in the caput, the company must file the claim, presenting evidence of the sending of the notification of the field action to ANVISA.

CHAPTER III
FINAL AND TRANSITIONAL PROVISIONS

Art. 8 The change of approval required will only take effect after the final decision is published in the Official Gazette and, when applicable, the updated data will be published on ANVISA's electronic portal.

Art. 9 The changes of immediate implementation will be published exclusively in the electronic portal of ANVISA, observing the deadline of up to 30 (thirty) days, counted from the

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finalization of the protocol of the respective petition, regardless of documentary analysis by ANVISA.

Art. 10. The petition for immediate implementation may be subject to documentary or fiscal evaluation at any time by ANVISA and, if necessary, additional information or clarification may be requested.

Single paragraph. ANVISA may suspend the marketing, importation and/or use of the product until its regularization in the event that there is inconsistency in the petition for change of immediate implementation that justifies such sanitary measure.

Art. 11. Petitions contemplated within the scope of this regulation filed before the effective date of this Resolution shall be analyzed in accordance with regulations in force at the time of the protocol.

Art. 12. Item 1 of Part 4 of the Technical Regulation of the Collegiate Board Resolution - RDC No. 185, of October 22, 2001, is hereby repealed.

Art. 13. This Resolution takes effect on April 1, 2020.

ANTONIO BARRA TORRES
Substitute Chief Executive Officer