MINISTRY OF HEALTH

NATIONAL HEALTH SURVEILLANCE AGENCY

BOARD

NORMATIVE INSTRUCTION - IN NO. 290, OF APRIL 4, 2024

Establishes, pursuant to the Resolution of the Collegiate Board of Directors - RDC No. 741, of August 10, 2022 , an optimized procedure for the purposes of analyzing and deciding on petitions for registration of medical devices, through the use of analyzes carried out by the Equivalent Foreign Regulatory Authority (AREE).

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, combined with article 7, III of Law No. 9,782, of January 26, 1999 , and article 187, VII, 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 Normative Instruction, as resolved at a meeting held on April 3, 2024, and I, Chief Executive Officer, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Goal

Art. 1 This Normative Instruction establishes, pursuant to the Resolution of the Collegiate Board of Directors - RDC No. 741, of August 10, 2022 , an optimized procedure for the purposes of analyzing and deciding on petitions for registration of medical devices, through the use of analyzes carried out by the Equivalent Foreign Regulatory Authority (AREE).

Sole Paragraph. The definition of medical devices includes medical devices for in vitro diagnosis, as provided for in the Resolution of the Collegiate Board of Directors - RDC No. 751, of September 15, 2022 , and its updates.

Section II

Scope

Art. 2 This Normative Instruction applies to the evaluation of primary petitions for registration of medical devices defined in the Resolution of the Collegiate Board of Directors - RDC No. 751, of September 15, 2022 , and its updates, including the medical devices for in vitro diagnosis defined in the Resolution of the Collegiate Board of Directors - RDC No. 830, of December 6, 2023 , and their updates, framed in Risk Classes III (high risk) and IV (maximum risk).

Art. 3 The optimized procedure referred to in this Normative Instruction is based on the prior authorization of medical devices by a recognized Equivalent Foreign Regulatory Authority (AREE).

Art. 4 This Normative Instruction does not apply to medical devices that have been authorized by AREE by means of an abbreviated rite that is similar to the optimized analysis procedure adopted by the National Health Surveillance Agency (Anvisa).

Sole Paragraph. The registration of the products referred to in the caput of this article will observe Anvisa's regular procedure, by ordinary means, provided for in the Resolution of the Collegiate Board - RDC No. 751, of September 15, 2022 , and its updates, or in the Resolution of the Collegiate Board - RDC No. 830, of December 6, 2023 , and its updates, depending on the type of medical device involved.

Section III

Definitions

Art. 5 For the purposes of this Resolution, the following definitions are adopted:

I – Equivalent Foreign Regulatory Authority (AREE): foreign regulatory authority or international entity that has regulatory practices aligned with those of Anvisa, responsible for ensuring that the products authorized for distribution have been properly evaluated and meet recognized standards of quality, safety and efficacy, and which will be considered by Anvisa in a practice of regulatory trust;

II – essentially identical medical device: device with essential characteristics identical to those approved by the reference regulatory authority, including those related to the quality of the product and its components, such as technical specifications (same qualitative and quantitative composition, physical, chemical, mechanical, electrical and biological properties), indications and intended use, manufacturer, manufacturing process, results of safety studies and performance;

III – instructive documentation: information presented by means of reports, reports, opinions or technical or legal documents of a decision-making, auxiliary or opinionative nature issued by the Equivalent Foreign Regulatory Authority for use in the optimized analysis procedure;

IV – technical dossier: document that describes the elements that make up the product, indicating the characteristics, purpose, mode of use, content, special care, potential risks, production process and additional information;

V – optimized analysis procedure: Anvisa's technical evaluation mechanism, facilitated by regulatory trust practices, which uses the technical analysis or instructional documentation issued by an AREE as the only or complementary reference;

VI – registration: a private act of Anvisa intended to prove the right to manufacture and import a product subject to the regime of Law No. 6,360, of September 23, 1976 , and classified in risk classes III or IV, with the indication of the name, manufacturer, purpose and other elements that characterize it; and

VII – ordinary way of analysis: full evaluation of the documents linked to the registration petitions (primary or secondary) of medical devices and medical devices for in vitro diagnosis filed with Anvisa, based on the requirements set forth in the Resolutions of the applicable Collegiate Board.

CHAPTER II

OF RECOGNIZED AREE

Art. 6 For the purposes of adopting the optimized analysis procedure, the following AREE and respective proofs of registration or authorization are considered:

I - Australia: Australia Therapeutic Goods Administration (TGA) - Australian Register of Therapeutic Goods (ARTG);

II - Canada: Health Canada (HC) - Medical Device Licence;

III - United States of America (USA): US Food and Drug Administration (US FDA) - 510(k) Clearance, Premarket Approval (PMA) or 513(f)(2) "De Novo"; and

IV - Japan: Japan Ministry of Health, Labour and Welfare (MHLW) - Pre-market approval (Shonin).

CHAPTER III

GENERAL REQUIREMENTS FOR THE ADOPTION OF THE OPTIMIZED PROCEDURE FOR THE ANALYSIS OF PETITIONS

Article 7 The optimized analysis procedure may be applied to medical device registration petitions that meet the following conditions:

I - the medical device must be authorized by at least one of the AREE listed in article 6 of this Normative Instruction; and

II - the documentation proving registration or authorization issued by AREE must refer to the medical device essentially identical to the one intended to be registered in the national territory, and include information related to the indication(s) of intended use/use and manufacturer(s).

CHAPTER IV

REQUEST FOR THE OPTIMIZED PROCEDURE FOR THE ANALYSIS OF PETITIONS

Article 8 The request for registration of a medical device via an optimized analysis procedure must be accompanied by the documents established by the Resolution of the Collegiate Board of Directors - RDC No. 751, of September 15, 2022 , and its updates, or Resolution of the Collegiate Board of Directors - RDC No. 830, of December 6, 2023 , and its updates, with the following complementary documentation:

I - declaration available in the Annex of this Normative Instruction, duly presented with the electronic signatures of the legal and technical representatives;

II - document proving registration or authorization issued by AREE, which must refer to the essentially identical medical device that is intended to be registered in the national territory and include information related to the indication(s) of intended use/use and manufacturer(s), and must be consularized or apostilled, and accompanied by a sworn translation when it is not written in Portuguese, English or Spanish; and

III - instructions for the use of the medical device adopted and in force in the jurisdiction of the AREE, accompanied by a sworn translation when it is not written in Portuguese, English or Spanish.

Art. 9 Anvisa, upon analysis of the instructive documentation issued by AREE, may opt for the use of the procedure of analysis by ordinary means of the documents submitted.

Sole Paragraph. The adoption of the analysis by ordinary means will be communicated to the company with the indication of the justification for the decision.

Article 10. The adoption of the optimized analysis procedure will not imply a change in the chronological order of the petitions.

Article 11. The complementary documentation indicated in article 8 must be filed as a secondary petition, with the subject of a specific amendment to comply with this Normative Instruction.

Sole Paragraph. The absence of a protocol of the amendment petition, referred to in the caput, will result in the analysis of the registration petition by ordinary means.

CHAPTER V

FINAL AND TRANSITORY PROVISIONS

Art. 12. The same requirements and typifications of sanitary infractions apply to medical devices registered through the optimized analysis procedure, including penalties, for the registration regime of medical devices and medical devices for in vitro diagnosis.

Article 13. The optimized analysis procedure established in this Normative Instruction preserves Anvisa's decision-making autonomy, whose decisions can be made independently of the decisions and conditions approved in the AREE.

Article 14. The use of the optimized analysis procedure does not exempt compliance with the legal requirements established in the current regulations.

Article 15. Registration petitions filed before the period of validity of this Normative Instruction, but which are pending technical analysis, may be analyzed by the optimized procedure, provided that the company petitions Anvisa for the matter of specific amendment, as established in article 11 of this Normative Instruction.

Article 16. Failure to comply with the provisions of this Normative Instruction constitutes an infraction of a sanitary nature, subjecting the offender to prosecution and penalties provided for in Law No. 6,437, of August 20, 1977, or legal instrument that may replace it, without prejudice to the applicable criminal and civil liabilities.

Article 17. This Normative Instruction enters into force on June 3, 2024.

ANTONIO BARRA TORRES
Chief Executive Officer

RET., 04/10/2024 - Section 1

ATTACHMENT

STATEMENT OF ASSESSMENT OF ELIGIBILITY FOR REVIEW OF MEDICAL DEVICE PETITIONS BY OPTIMIZED REVIEW PROCEDURE

The company XXXXXXXX, CNPJ XXXXXXXXXXXX, requests analysis of the petition for file number XXXXXXXXXX, through an optimized analysis procedure, as indicated below:

Regulatory Authority(ies) that have approved/authorized the medical device for which the application for optimized pathway evaluation is being made:	
AREE Reference:	
Name(s) of the device(s), as regularized by AREE:	
Indications for use as approved by AREE (in Portuguese):	

I am aware that Anvisa may, according to the technical evaluation of the information provided, adopt the ordinary way of analysis.

I declare that I have complied with the provisions of the sanitary regulations for medical devices, in accordance with the regulatory category established in Brazil, with regard to the documentation and performance of the studies and tests required at the time of the filing of the petition, as well as that I am committed to maintaining technovigilance and continuous monitoring with regard to ensuring the maintenance of essential safety and performance requirements.

I also declare that the medical device object of this claim is essentially identical to the one approved by the reference AREE, under the terms of Anvisa Normative Instruction No. 290, of April 4, 2024 .

The company, in the persons of its legal and technical representatives, ensures and is responsible for the veracity and reliability of the information provided herein, being aware that it is responsible for the quality, safety and performance of the medical devices registered by it, ensuring that they are suitable for the purposes for which they are intended, comply with the requirements established in their registration and do not put patients at risk because they are safe, inadequate quality or performance, and that any inconsistencies between the information provided herein and the registration process of the medical device may cause a change in the decision, recall of batches, suspension of manufacture and/or commercialization, cancellation of registration and other penalties under the terms of Law No. 6,437, of August 20, 1977 and its updates, without prejudice to other penalties provided for by law.

Date:__/__/____

Advanced or qualified electronic signature of the Technical Responsible: _____

Advanced or qualified electronic signature of the Legal Guardian: _____

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This text does not replace the Official Publication.