Normative Instruction – IN no. 290 of 4 April 2024

Establishes, in the terms of Collegiate Board Resolution – RDC no. 741 of 10 August 2022, optimized procedures for the purposes of analysis and decision-making regarding petitions for marketing authorization for medical devices, by taking advantage of analyses carried out by an Equivalent Foreign Regulatory Authority (EFRA).

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, and Article 7, item III of Law no. 9,782 of 26 January 1999, and item VII, paragraph 1 of Article 187 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Normative Instruction, as decided upon in a meeting held on 3 April 2024, and I, Director-President, determine its publication.

## CHAPTER I

## INITIAL PROVISIONS

### Section I

### Objective

Article 1. This Normative Instruction establishes, in the terms of Collegiate Board Resolution – RDC no. 741 of 10 August 2022, optimized procedures for the purposes of analysis and decision-making regarding petitions for marketing authorization for medical devices, by taking advantage of analyses carried out by an Equivalent Foreign Regulatory Authority (EFRA).

Sole paragraph. The definition of medical devices includes *in vitro* diagnostic medical devices, in accordance with the provisions of Collegiate Board Resolution – RDC no. 751 of 15 September 2022 and its updates.

### Section II

### Scope

Article 2. This Normative Instruction applies to the analysis of primary petitions for the marketing authorization for medical devices defined in Collegiate Board Resolution – RDC no. 751 of 15 September 2022 and its updates, including *in vitro* diagnostic medical devices defined in Collegiate Board Resolution – RDC no. 830 of 6 December 2023 and its updates, classified as Risk Class III (high risk) and IV (maximum risk).

Article 3. The optimized procedure addressed in this Normative Instruction is based on the previous authorization of medical devices by a recognized Equivalent Foreign Regulatory Authority (EFRA).

Article 4. This Normative Instruction does not apply to medical devices that have been authorized by the EFRA through an abbreviated procedure similar to the optimized analysis procedure adopted by the Brazilian Health Regulatory Agency (Anvisa).

Sole paragraph. The product marketing authorization referred to in the caption of this article shall observe Anvisa regular procedure, through the ordinary analysis procedure, provided for in Collegiate Board Resolution – RDC no. 751 of 15 September 2022 and its updates, or Collegiate Board Resolution – RDC no. 830 of 6 December 2023 and its updates, depending on the type of medical device at issue.

**Section III**

**Definitions**

Article 5. For the purposes of this Normative Instruction, the following definitions are adopted:

I – Equivalent Foreign Regulatory Authority (EFRA): foreign regulatory authority or international organization with regulatory practices aligned with Anvisa's, which is responsible for ensuring that the products authorized for distribution were appropriately assessed and meet recognized standards of quality, safety, and efficacy, and which shall be considered by Anvisa in a practice of regulatory reliance.

II – essentially identical medical device: device with essential characteristics identical to the one approved by the reference regulatory authority, including those related to 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 from safety and performance studies;

III – application documents: information presented through reports, opinions, or technical/ legal documents of 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 of the product, indicating characteristics, purpose, mode of use, content, special precautions, potential risks, manufacturing process, and additional information;

V – optimized analysis procedure: technical assessment mechanism at Anvisa, facilitated by regulatory reliance practices, which uses technical analysis or application documents issued by an Equivalent Foreign Regulatory Authority as sole or complementary reference;

VI – marketing authorization: Anvisa exclusive act intended to prove the right to manufacture and import a product subject to the provisions of Law no. 6,360 of 23 September 1976, and classified as risk class III or IV, including the name, manufacturer, purpose, and other elements characterizing such product; and

VII – ordinary analysis: whole assessment of documents attached to (primary or secondary) petitions for marketing authorization for medical devices and *in vitro* diagnostic medical devices

made to Anvisa, based on the requirements provided for in the applicable Collegiate Board Resolutions.

**CHAPTER II**

**RECOGNIZED EQUIVALENT FOREIGN REGULATORY AUTHORITIES**

Article 6. For the purposes of adopting the optimized analysis procedure, the following EFRAs and their respective evidence of approval or marketing 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 ANALYSIS PROCEDURE OF PETITIONS**

Article 7. The optimized analysis procedure may be applied for petitions for marketing authorization for medical devices meeting the following conditions:

I – the medical device must have been approved by at least one of the EFRAs listed in Article 6 of this Normative Instruction; and

II – the regulatory documentation confirming approval or marketing authorization issued by the recognized EFRA must refer to the medical device essentially identical to the one intended to be granted marketing authorization in Brazilian territory and include the information related to use indication(s)/ intended use and manufacturer(s).

**CHAPTER IV**

**APPLICATION FOR THE OPTIMIZED ANALYSIS PROCEDURE OF PETITIONS**

Article 8. The application for marketing authorization for a medical device through the optimized analysis procedure must be submitted with the documentation established by Collegiate Board Resolution – RDC no. 751 of 15 September 2022 and its updates, or Collegiate Board Resolution – RDC no. 830 of 6 December 2023 and its updates, with the following complementary documents:

I – declaration available in the Annex to this Normative Instruction, duly presented with the electronic signatures of the legal and technical responsible officers;

II – document confirming approval or marketing authorization issued by the recognized EFRA, which must refer to the medical device essentially identical to the one intended to be granted marketing authorization in Brazilian territory and include the information related to use indication(s)/ intended use and manufacturer(s), and it must be consular or certified, accompanied by official translation when it is not written in Portuguese, English, or Spanish; and

III – medical device use instructions adopted and valid in the EFRA jurisdiction, accompanied by official translation when it is not written in Portuguese, English, or Spanish.

Article 9. Anvisa, when analyzing the regulatory documentation issued by the EFRA, may choose to apply the ordinary analysis procedure to the documents submitted.

Sole paragraph. Anvisa shall communicate to the company about the adoption of ordinary analysis, with a justification for such decision.

Article 10. Adoption of the optimized analysis procedure shall not imply alteration of the chronological order of petitions.

Article 11. The complementary documents referred to in Article 8 must be protocolized as secondary petition with a specific addition subject, in compliance with this Normative Instruction.

Sole paragraph. The lack of protocol of the additional secondary petition referred to in the caption of this article shall lead to ordinary analysis of the petition for marketing authorization.

**CHAPTER V**

**FINAL AND TRANSITIONAL PROVISIONS**

Article 12. The same requirements and classifications of health infractions, including sanctions, applied to the regimen of marketing authorization of medical devices and *in vitro* diagnostic medical devices are applicable to the medical devices granted marketing authorization through the optimized analysis procedure.

Article 13. The optimized analysis procedure established in this Normative Instruction maintains Anvisa decision autonomy, and the agency's decisions may be taken regardless of decisions and conditions approved by the EFRAs.

Article 14. Adoption of the optimized analysis procedure does not waive compliance with the legal requirements established in the regulations in force.

Article 15. The marketing authorization petitions submitted before this Normative Instruction enters into force, but pending technical analysis, may be reviewed through optimized procedure, as long as the company submits to Anvisa a petition with a specific addition, as established in Article 11 of this Normative Instruction.

Article 16. Failure to comply with the provisions contained in this Normative Instruction constitutes a health infraction, and the offender is subject to lawsuit and penalties provided for in Law no. 6,437 of 20 August 1977, or legal instrument substituting it, without prejudice to the applicable criminal and civil liabilities.

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

**ANTONIO BARRA TORRES**

**DIRECTOR- PRESIDENT**

**ANNEX**

**DECLARATION OF ASSESSMENT OF PETITION ELIGIBILITY TO OPTIMIZED ANALYSIS PROCEDURE**

Company XXXXXXXXXXXXXXX, holder of CNPJ no. XXXXXXXXXXXXXXXX, requests analysis of petition no. XXXXXXXXXX through the optimized analysis procedure, indicated as follows:

| | |
|---|---|
| Regulatory Authority(ies) that approved/ authorized the medical device object of the request for optimized analysis procedure: | |
| Reference EFRA: | |
| Name(s) of the device(s), as regularized by the EFRA: | |
| Indications of use as approved by the EFRA (in Portuguese): | |

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

I hereby declare that the provisions of health regulations on medical devices have been complied with, in accordance with the regulatory category established in Brazil, regarding documentation and conduction of studies and evidence required at the time the petition was submitted. I also declare my commitment to keep continuous technical surveillance and monitoring to ensure that essential safety and performance requirements are maintained.

In addition, I hereby declare that the medical device object of this request is essentially identical to the one approved by the reference EFRA, in the terms of Anvisa Normative Instruction no. 290 of 4 April 2024.

The company, represented by its legal and technical responsible officers, guarantees and accounts for the veracity and reliability of the information provided herein, and is aware of its responsibility for the quality, safety, and performance of its medical devices granted marketing authorization. The company ensures such medical devices are adequate for their intended purpose, comply with the requirements established in their marketing authorization document, and do not put patients at risk due to inadequate safety, quality, or performance. Eventual inconsistencies between the information provided herein and the medical device marketing authorization process may lead to alteration of decision, withdrawal of batches, suspension of manufacture and/ or commercialization, cancellation of marketing authorization, and other penalties in the terms of Law no. 6,437 of 20 August 1977 and its updates, without prejudice to other penalties provided for in the legislation in force.

Date: ____/ _____/ _____

Advanced or qualified electronic signature by the Technical Responsible Officer:

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Advanced or qualified electronic signature by the Technical Responsible Officer:

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