RDC RESOLUTION No. 579, OF NOVEMBER 25, 2021

Provides for the import, marketing, and donation of used and refurbished medical devices.

The Collegiate Board of Directors of the National Agency of Sanitary Surveillance, in the use of the powers conferred upon it by art. 15, III and IV, allied to art. 7, III and IV of Law No. 9782, of January 26, 1999, and art. 53, VI, Paragraphs 1 and 3 of the Internal Regulations approved by the Collegiate Board of Directors Resolution - RDC No. 255, of December 10, 2018, hereby agrees to adopt the following Resolution, as resolved at a meeting held on November 25, 2021, and I, the Chief Executive Officer, hereby determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

PURPOSE

Art. 1 This Resolution defines the requirements for the import, marketing, and donation of used or refurbished medical devices intended for use in Brazil.

Section II

SCOPE

Art. 2 This Resolution is applicable to products regulated by the Collegiate Board of Directors Resolution - RDC No. 185, of October 22, 2001, and Collegiate Board of Directors Resolution - RDC No. 36, of August 26, 2015, or in resolutions that may replace them.

Sole paragraph. The technical assistance activity is not part of the scope of this regulation.

Section III

DEFINITION

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

I. Leasing: a legal transaction carried out between a legal entity, in the capacity of lessor, and an individual or legal entity, in the capacity of lessee, through which the former, owner of movable or immovable property, assigns to the latter the use of the asset, through the transfer of its direct possession, in exchange for periodic payment, being assured, at the end of the contractual term, the renewal of the agreement, the return of the asset, or its purchase at the advanced residual price;

II. Technical Assistance: Maintenance or repair of a finished product in order to return it to its specifications for the same customer;

III. Marketing: any activity that involves sale, trade in, lease, loan for use, or lease-purchase agreement;

IV. Loan for Use: it is the free loan of equipment, which shall be repaid within the time agreed by the parties;

V. Trade in: agreement entered into between creditor and debtor, through which the creditor consents to receive payment other than what is owed to it;

VI. Medical Device for lay use: medical device for personal use that does not depend on professional assistance or specialized training for its use, as specified in the product regularized by Anvisa;

VII. Medical Device for professional use: medical device that requires specialized training, support, or assistance from a health professional for its use, as specified by Anvisa;

VIII. Implantable Medical Device: any device, including those that are partially or fully absorbed, intended: a) to be fully introduced into the human body; or b) to replace an epithelial surface or the ocular surface, through clinical intervention, and intended to remain in this location after the intervention. An implantable device is also considered to be any device intended to be partially introduced into the human body through clinical intervention and to remain in this location after the intervention for a period of at least 30 days;

IX. Medical Device: any instrument, appliance, equipment, implant, in vitro diagnostic device, software, material, or other item, intended by the manufacturer to be used, alone or together, in human beings, for any of the following specific medical purposes: a) diagnosing, preventing, monitoring, treating (or alleviating) a disease; b) diagnosis, monitoring, treatment, or repair of an injury or disability; c) investigation, replacement, alteration of the anatomy, or of a physiological or pathological process or state; d) support or sustain life; e) childbirth control or support; f) provide information through in vitro examination of samples from the human body, including organ and tissue donations; g) and whose main intended action is not achieved by pharmacological, immunological, or metabolic means in the human body, but which can be aided in its intended action by such means. Notes: a) active products (equipment) specifically intended for cleaning, disinfecting, or sterilizing medical devices are considered medical devices; b) active products (equipment) indicated for aesthetic correction and beautification are considered medical devices;

X. Donation: a contract by which the donor, by liberality, freely transfers the equipment owned by it to the property of another person, the donee;

XI. Refurbished equipment: in vitro diagnostic equipment or instrument resulting from an industrial process carried out by the original manufacturer of the new product, by a company belonging to the same corporate group or by a company qualified and authorized by the original manufacturer specifically for this process, involving, when necessary:
a) the repair, rework, replacement of worn-out parts and software/hardware upgrade of used products, to the extent necessary to determine the state of conservation of its components and parts; and b) the replacement of critical and/or worn-out components with new or refurbished components, so that the resulting refurbished asset will have operating, functioning and performance conditions equivalent to the specifications of the original new asset, including in terms of warranty;

XII. Regulated equipment: equipment or instrument for in vitro diagnostics registered or notified by Anvisa, in compliance with current health legislation;

XIII. Used equipment: equipment or instrument for in vitro diagnostics that has already been used, and that has not been subjected to any refurbishing process;

XIV. In vitro diagnostics instrument: equipment or device developed with the intention of being used as a medical device for in vitro diagnostics;

XV. Lease: contract whereby one of the parties assigns to the other the use and enjoyment of the medical equipment or in vitro diagnostic instrument, for a fixed or indefinite period, upon certain retribution;

XVI. Health service: activity in which assistance is provided to the individual or human population that may change their state of health, aiming at the prevention and diagnosis of diseases, treatment, recovery, aesthetics, or rehabilitation, compulsorily performed by health professionals, or under their supervision. Note: Activities that are not exclusive to health professionals, but that use the equipment covered in this Resolution in their practice, are equivalent to Health Services;

XVII. Manufacturing unit for refurbishing: establishment where the manufacturing or manufacturing stage of the refurbished equipment takes place;

XVIII. Sale: transfer of ownership of the equipment upon payment. CHAPTER II

PROHIBITIONS

Art. 4 The import, marketing, and donation of used or refurbished medical devices that do not meet the criteria established in this Regulation are prohibited nationwide.

Sole paragraph. Used equipment that is intended exclusively for the refurbishing process nationwide can be imported, as provided by the Collegiate Board of Directors Resolution - RDC No. 81, of November 5, 2008, or in a resolution that may replace it.

Art. 5 The import, marketing, and donation of used or refurbished medical devices, which are classified as Implantable Medical Devices - DMI, are prohibited nationwide.

CHAPTER III

MARKETING AND DONATION OF USED EQUIPMENT

Art. 6 The marketing and donation of used equipment for professional or lay use that has been regularized by Anvisa is permitted.

Paragraph 1 Used equipment shall have an indelible tag preserved, in order to allow traceability and identification of its regularization number at Anvisa.

Paragraph 2 The marketing and donation of used equipment for professional use is only allowed to companies regularized by Anvisa through a Company Operating Authorization - AFE, with the activity of distributing medical devices and health services.

Art. 7 Transportation requirements shall be guaranteed by the service or company that sells or donates the equipment, or by the service or company that receives it, as defined in an agreement between the parties.

Paragraph 1 The health service that receive it is responsible for complying with the installation requirements, ensuring the proper functioning of the equipment.

Paragraph 2 Transportation and installation requirements shall follow the manufacturer's guidelines.

Art. 8 The health service or company that sells or donates used equipment for professional use, classified in risk classes I or II, pursuant to the classification provided by the Resolutions listed in art. 2 of this Resolution, is responsible for ensuring that it is only available for use after assessment by a professional holding a higher education degree, qualified and with proven technical expertise, with Technical Term of Responsibility - ART, guaranteeing the technical-operational and safety conditions.

Sole paragraph. The issuance of the Technical Term of Responsibility - ART is waived for the transfer of equipment between legal entities belonging to the same economic group, or between branches, without prejudice to the compliance with other obligations provided for in this regulation.

Art. 9 The health service that receives the used equipment for professional use referred to in this Resolution shall formally communicate such act to the company holding the notification or registration of the equipment with Anvisa, even if the regularization is not in force, within a period of up to thirty (30) days, counted from the receipt of the equipment.

Sole paragraph. The communication referred to in the head provision shall contain the name of the health service that receives the used equipment for professional use, the CNPJ (Corporate Taxpayer Registration), address, and the model and serial number of the equipment, being required to maintain the record of this act.

Art. 10. The health service that receives used equipment for professional use shall comply with the provisions established by the Collegiate Board of Directors Resolution - RDC No. 509, of May 27, 2021, which provides for the management of health technologies in healthcare establishments, or their replacements.

Art. 11. For the marketing and donation of used equipment for professional use classified in risk classes III or IV, pursuant to the classification provided for in the Resolutions listed in art. 2 of this Resolution, a technical report is required attesting that it complies with the technical specifications and conditions of use defined by the manufacturer.

Sole paragraph. Diagnostic or interventional radiology equipment, which comply with the Collegiate Board of Directors Resolution - RDC No. 330, of December 20, 2019, and its related Normative Instructions, or their replacements, are exempt from the technical report, provided that the assessment is performed by a professional holding a higher education degree, with the Technical Term of Responsibility - ART.

Art. 12. The leasing and loan for use company shall keep a record of equipment distribution, as well as preventive and corrective maintenances, observing the criteria for replacement and restocking of parts, calibrations and periodicity of actions, ensuring performance and traceability conditions.

Sole paragraph: For lease or loan for use activities, the compliance with the provisions of Art. 8 and 11 of this Resolution is waived.

CHAPTER IV

TECHNICAL REPORT FOR MARKETING AND DONATION OF USED EQUIPMENT

Art. 13. The issuance of a technical report for the marketing and donation of used equipment referred to in this Resolution is mandatory by the Brazilian company holding the notification or registration of the equipment with ANVISA, or by a company authorized by it, or by the manufacturer responsible for the equipment.

Art. 14. The technical report shall be prepared in Portuguese, providing, at least, the following information:

I. Equipment data: trade name, model, serial/batch number, registration number at Anvisa;

II. Owner's data of the assessed unit;

III. Data of the company that issued the technical report: trade name, address, CNPJ, telephone, identification, and registration number of the respective class council of the professional responsible for preparing the technical report;

IV. Issuance date of the technical report;

V. Clear and objective conclusion of the general condition of the unit assessed, informing whether or not it complies with the technical specifications and conditions of use defined by the manufacturer;

VI. General guidelines for correct transport and installation, highlighting specific requirements, when applicable, defined by the manufacturer.

Paragraph 1 At least two copies of the technical report shall be issued, one kept by the seller/donor, and the other by the company or health service that receives the equipment.

Paragraph 2 The transfer of equipment between legal entities belonging to the same economic group, or between branches, is exempt from the issuance of a technical report, without prejudice to the other obligations provided for in this regulation.

CHAPTER V

EQUIPMENT REFURBISHING

Art.15. The import, manufacture, and marketing of refurbished equipment with regularization by Anvisa in force are permitted.

Sole paragraph. The manufacturing unit for refurbishing shall be included in the regularization of the equipment with Anvisa.

Art. 16. Refurbished equipment that has its production line discontinued is exempt from the requirement of compulsory certification established by the Collegiate Board of Directors Resolution - RDC No. 549, of August 30, 2021, or its replacements.

Sole paragraph. It shall be submitted to the Anvisa area responsible for the regularization of the equipment, by means of a specific petition, a statement from the manufacturer informing the intention to maintain the refurbishing line.

Art. 17. Initial regularization shall not be granted exclusively for refurbished equipment, and the valid registration may be maintained under the conditions provided for in art. 16 of this Resolution.

Art. 18. The manufacturing unit performing the refurbishing activity shall indelibly affix to each equipment the complementary information that the unit was refurbished, indicating the year in which the refurbishing was performed.

Sole paragraph. If it is impossible to affix the indelible tag to the equipment due to physical limitations, it is mandatory to affix the tag to the product's primary packaging.

CHAPTER VI

USE AFTER THE EXPIRATION OF THE REGULARIZATION TERM

Art. 19. The use of a medical device, regularly purchased, even after the expiration of its regularization term with Anvisa, is hereby permitted.

Sole paragraph. For the purposes provided for in the head provision, the compliance with the sanitary provisions, technical specifications, and conditions of use defined by the manufacturer is required, in order to ensure the proper functioning of the product.

CHAPTER VII

FINAL AND TRANSITIONAL PROVISIONS

Art. 20. Non-compliance with the provisions contained in this Normative Instruction constitutes health infraction, pursuant to Law no. 6,437, of August 20, 1977, without prejudice to the applicable civil, administrative and criminal liabilities.

Art. 21. The Collegiate Board of Directors Resolution - RDC No. 25, of February 15, 2001.

Art. 22. This Resolution shall enter into force on January 1, 2022.

Sole paragraph. A period of three hundred and sixty-five (365) days is established for companies that perform lease and loan for use activities to adapt to art. 6 of this Resolution.

ANTONIO BARRA TORRES