Ministry of Health - MS

National Health Surveillance Agency – ANVISA

COLLEGIATE BOARD RESOLUTION - RDC No. 579, OF NOVEMBER 25, 2021

(Published in DOU nº 225, of December 1, 2021)

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

The **Collegiate Board of the National Health Surveillance Agency** does not make use of duties conferred by art. 15, III and IV, combined with art. 7th, III and IV of Law No. 9,782, of January 26, 1999, and art. 53, VI, §§ 1 and 3 of the Internal Regulations approved by Collegiate Board Resolution - RDC nº 255, of December 10, 2018, resolves to adopt the following Resolution, as resolved in a meeting held on November 25, 2021 and I, Chief Executive Officer, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

GOAL

Art. 1 This Resolution defines the requirements for importing, selling and donating used or refurbished medical devices intended for use in Brazil.

Section II

COVERAGE

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

Single paragraph. Technical assistance activity is not part of the scope of this specificity.

Section III

DEFINITIONS

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

I. Leasing: legal transaction carried out between a legal entity, in the as lessor, and an individual or legal entity, as lessee, through which the first, owner of movable or immovable property, transfers the use of the asset to the latter, through the transfer of direct possession, in exchange for periodic payment, ensuring, at the end of the contract term, renewal of the agreement, the return of the thing or its acquisition at the residual price advanced;

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

III. Commercialization: any activity involving sale, giving in payment (trade in), rental, lending or leasing;

4. Lending: is the free loan of equipment, which must be repaid over time agreed by the parties;

V. Payment in payment (trade in): agreement agreed between creditor and debtor through the which the creditor consents to receive a benefit other than what is owed to him;

SAW. Medical device for lay use: medical device for personal use that does not depend on professional assistance or specialized training for its use, according to the specification defined in the product regularized with Anvisa;

VII. Medical Device for professional use: medical device that requires training specialized support or assistance from a healthcare professional for its use, according to its specification with Anvisa;

VIII. Implantable Medical Device: any device, including those that are partial or fully unlocked, intended: a) to be fully implanted in the human body; or b) replace an epithelial surface or an ocular surface, through clinical intervention, and which is intended to remain in this location after the intervention. Any device intended to be partially installed in the human body through clinical intervention and permanence in this location after intervention for a period of at least 30 days;

IX. Medical Device: any instrument, apparatus, equipment, implant, device for in vitro diagnostic software, material or other article, intended by the manufacturer to be used, isolated or jointly, in humans, for some of the following specific medical purposes: a) diagnosis, prevention,

monitoring, treating (or stopping) a disease; b) diagnosis, monitoring, treatment or accessories of an injury or disability; c) investigation, replacement, alteration of anatomy or a physiological or pathological process or state; d) support or sustain life; e) control or support for design; 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 assisted in their intended action by such means. Notes: a) active products (equipment) specifically intended for cleaning, infecting or sterilizing medical devices are considered medical devices; b) active products (equipment) indicated for aesthetic correction and beautification are considered medical devices;

X. Donation: contract by which the donor, out of liberality, transfer freely the equipment of his property to the property of others, the grantee;

XI. Refurbished equipment: equipment or instrument for in-house diagnostics vitro 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 committed to and authorized by the original manufacturer specifically for this process, involving, when necessary: a) repair, rework, replacement of worn parts and updating software/ hardware of used products, to the extent necessary to determine the state of conservation of their components, parts and pieces; and b) the replacement of critical and/or worn components with new or reconditioned components, so that the reconditioned good results in operating, functioning and performance conditions equivalent to the specifications of the original new good, including in terms of warranty;

XII. Regulated equipment: equipment or instrument for in-depth diagnosis vitro registered or notified with Anvisa in accordance with current health legislation;

XIII. Equipment used: in vitro diagnostic equipment or instrument that has already been used, and has not been required to undergo any reconditioning process;

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

XV. Location: contract by which one party grants the use and enjoyment of the property to another medical equipment or in vitro diagnostic instrument, for a fixed or indefinite period, for a certain remuneration;

XVI. Health service: activity in which assistance is provided to individuals or to the human population that may alter their health status, aiming at the prevention and diagnosis of diseases, treatment, recovery, aesthetics or rehabilitation, carried out obligatorily by a health professional 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 equated to Health Services;

XVII. Reconditioning plant: the establishment where the manufacturing or manufacturing stage of refurbished equipment takes place;

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

CHAPTER II

PROHIBITIONS

Art. 4th The importation, commercialization and donation of used or refurbished medical devices that do not meet the criteria of this Regulation.

Single paragraph. Used equipment that is intended for exclusively to the reconditioning process in national territory, in accordance with the criteria established in the Collegiate Board Resolution - RDC nº 81, of November 5, 2008, or in a resolution that replaces it.

Art. 5th The importation, commercialization and donation of used or refurbished medical devices, which qualify as Implantable Medical Devices - DMI.

CHAPTER III

SALE AND DONATION OF USED EQUIPMENT

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

§ 1 The equipment used must have an indelible label preserved from way to allow traceability and identification of your regularization number at Anvisa.

§ 2 The sale and donation of used equipment for professional use are permitted only to companies regularized with Anvisa through a Company Operating Authorization - AFE with activity distributing medical devices and health services.

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

§ 1 The health service you receive is responsible for meeting the installation requirements, ensuring proper operation of the equipment.

§ 2 Transport and installation requirements must follow the guidelines of the manufacturer.

Art. 8º The health service or company that sells or makes equipment used for professional use classified in risk classes I or II, according to the classification contained in the Resolutions listed in art. 2 of this Resolution, is responsible for ensuring that it is only made available for use after evaluation by a higher-level, qualified professional with proven technical expertise, with a Technical Responsibility Note - ART, guaranteeing technical-operational and safety conditions.

Single paragraph. The issuance of the Responsibility Note is waived Technical - ART for transferring equipment between legal entities belonging to the same economic group, or between branches, without prejudice to the fulfillment of other obligations set out in this regulation.

Art. 9th The health service that receives the used equipment The professional referred to in this Resolution must formally communicate this 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 30 (thirty) days, counting from the collection of the equipment.

Single paragraph. The communication referred to in the caput must contain the name of the health service that receives used equipment for professional use, the CNPJ, address, and the model and serial number of the equipment, with the maintenance of a record of this act being mandatory.

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

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

Single paragraph. Diagnostic or interventional radiology equipment, which comply with the Collegiate Board Resolution - RDC nº 330, of December 20, 2019 and its Instructions Related regulations or their substitutes are exempt from the technical report as long as the evaluation is carried out by a higher-level professional with a Technical Responsibility Note - ART.

Art. 12. The leasing and leasing company must maintain the distribution record of the equipment, as well as preventive and corrective maintenance, respecting the criteria for replacement and organization of parts, calibrations and frequency of actions, ensuring performance and traceability conditions.

Sole paragraph: For rental or lending activities, it is compliance with the provisions of Articles 8 and 11 of this Resolution is not required.

CHAPTER IV

TECHNICAL REPORT FOR SALE AND DONATION OF USED EQUIPMENT

Art. 13. It is mandatory to issue a technical report for the sale and donation of used equipment referred to in this Resolution 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 must be modified in Portuguese and contain, at least, The following information:

I. Equipment data: commercial name, model, serial/batch number, serial number registration with Anvisa;

II. Details of the owner of the evaluated unit;

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

4. Technical report issuance data;

V. Clear and objective conclusion of the general condition of the evaluated unit, stating whether it is whether or not it meets the technical specifications and conditions of use defined by the manufacturer;

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

§ 1 At least two copies of the technical report must be issued, one of which will be maintained by the seller/donor and the other by the company or health service that receives the equipment.

§ 2 The transfer of equipment between legal entities belonging to the same economic group, or between branches, without prejudice to the other obligations of this regulation.

CHAPTER V

EQUIPMENT RECONDITIONING

Art. 15. The import, manufacture and sale of refurbished equipment that is currently regularized with Anvisa.

Single paragraph. The reconditioning manufacturing unit must 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 for compulsory certification required by Collegiate Board Resolution - RDC nº 549, of August 30, 2021, or its substitutes.

Single paragraph. It must be presented to the Anvisa area responsible for regularizing the equipment, through a specific petition, declaration from the manufacturer informing the intention of maintain the reconditioning line.

Art. 17. Initial regularization will not be granted exclusively for equipment reconditioned, and the valid registration may be canceled under the conditions set out in art. 16 of this Resolution.

Art. 18. The manufacturing unit that carries out a reconditioning activity must establish in each equipment, indelibly, additional information that the unit was reconditioned, establishing the year in which the reconditioning was carried out.

Single paragraph. If it is impossible to affix an indelible label to the equipment for reasons physical limitations, it is mandatory to affix the label to the product's primary packaging.

CHAPTER VI

USE AFTER REGULARIZATION EXPIRES

Art. 19. The use of the medical device purchased regularly, even after the end of monitoring its regularization with Anvisa.

Single paragraph. For the purposes of the caput, it is mandatory to comply with the provisions sanitary conditions, technical specifications and conditions of use defined by the manufacturer, in order to guarantee the proper functioning of the product.

CHAPTER VII

OF THE FINAL AND TRANSITIONAL PROVISIONS

Art. 20. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, under the terms of Law No. 6,437, of August 20, 1977, without prejudice to civil, administrative and applicable penalties.

Art. 21. The Collegiate Board Resolution - RDC nº 25, of February 15, is hereby revoked. 2001.

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

Single paragraph. A period of 365 (three hundred and sixty-five) days is provided for companies that carry out rental and lending activities comply with art. 6th of this Resolution.

ANTÔNIO BARRA TORRES