RESOLUTION - RDC N º 185 FROM OCTOBER 22, 2001

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The Collegiate Directorate of the National Sanitary Surveillance Agency in the exercise of the powers granted under Article 11, Item IV, of the Resolution of the National Sanitary Surveillance Agency approved by Decree n° 3.029 dated April 16, 1999, at a meeting held on October10, 2001

WHEREAS the need to update the procedures for registration of "*Related Supplies*" matter of the Law N° 6.360 from September 23, 1976, Decree N° 79.094 dated January 5, 1977 and government decree *Portaria Conjunta* SVS/SAS N° 1, January 23, 1996;

WHEREAS the need to internalize the GMC Resolution N° 40/00 of MERCOSUR, which deals with registration of medical devices,

adopts the following Collegiate Directorate Resolution and I, in the capacity of Director-President, determine its publication:

Article 1 Approve the Technical Regulations contained in the annex to this resolution, which deals with registration, alteration, revalidation and cancellation of registration of medical devices through the National Health Surveillance Agency - ANVISA.

Sole Paragraph Other products for health defined as "*Related Supplies*" by Law N° 6.360/76 and Decree N° 79.094/77 are equivalent to medical devices for the application of this Resolution, except for in-vitro diagnostic reagents.

Article 2 The manufacturer or importer of medical devices must submit to ANVISA documents for registration, alteration, revalidation or cancellation of registration, the related items 5, 6, 9, 10 and 11 of Part 3 of the Regulation annexed to this resolution.

Paragraph 1 The following information provided in the documents mentioned in this article must be presented in text and be submitted in electronic media to be provided by ANVISA in its website, for the worldwide network of communication:

a) Form of the manufacturer or importer of medical devices - FFIPM as in Annex III.A of Technical Regulation;
b) labels and instructions for use, described in Annex III.B of the Technical Regulation.

Paragraph 2 The distributor of medical devices that request registration of product manufactured in Brazil, equates to the importer for the submission of the documentation referred to in this article.

Article 3 The manufacturer or importer of products exempt from registration contained in relations provided by ANVISA, as provided for in Law N° 6.360/76 and Decree N° 79.094/77 must make a cadastre their products in the Agency, submitting, in addition to the proof of payment of the fee for supervision pertinent, the information required in Article 2, paragraph 1 of this Resolution.

Sole Paragraph The modification, revalidation or cancellation of registration of the product mentioned in this article must follow the same procedures provided in paragraphs 9, 10, 11 and 13 of Part 3 of the Regulation annexed to this resolution, subject to the provisions of Parts 4 and 5 of these Regulations.

Article 4 In the case of medical equipment, the manufacturer or importer must fix indelibly in a visible place outside of the equipment, at least the following labeling information:
a) Identification of the manufacturer (name or mark);
b) Identification of the equipment (name and business model);
c) Serial number of equipment;
d) Registration number of the equipment at ANVISA.

Article 5 The petitions for registration, exemption, modification, revalidation or cancellation of registration, presented at ANVISA until 30 (thirty) days from the date of the publication of this resolution shall be subject to the *Portaria Conjunta* SVS/SAS N° 1/96 and *Portaria* SVS N° 543/97.

Sole Paragraph The petition for revalidation of the registration of medical device filed after the 30 (thirty) days referred on this must adapt the information in the original process to the provisions on this resolution and to the requirements of the specific technical regulations for the product, published during the validity of the registration.

Article 6 This Resolution shall enter into force on the date of its publication.

Article 7 Is hereby revoked the *Portaria Conjunta* SVS/SAS N° 1, from January 23, 1996 and the *Portaria* SVS N° 543 of October 29, 1997, after thirty (30) days from date of the publication of this Resolution.

GONZALO VECINA NETO

ANNEX

TECHNICAL REGULATION

REGISTRATION, ALTERATION, REVALIDATION OR CANCELLATION OF REGISTRATION OF MEDICAL DEVICES

PART 1 - Scope and Definitions

1. The provisions of this document are applicable to manufacturers and importers of medical devices.

2. The classification, procedures and specifications described in this document, for proposes of registration, apply to medical devices and accessories, as defined in Annex I.

3. For purposes of this document are adopted the definitions set forth in Annex I.

4. This document does not apply to medical devices used or reconditioned.

PART 2 - Classification

1. The medical devices, subject of this document, are framed according to the intrinsic risk they represent to consumer health, patient, operator or others involved, in Classes I, II, III or IV. To fit a medical device in one of these classes, must be applied the classification rules described in Annex II of this document.

2. In case of doubt in the classification, resulting from applying the rules described in Annex II shall be the responsibility of ANVISA to fit the medical device correctly.

3. The classification rules described in Annex II of this document may be updated, according to the administrative procedures adopted by ANVISA, taking into account technological progress and the notification of adverse events associated with the use or application of medical devices.

PART 3 - Procedures for Registration

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1. It is mandatory to register all medical devices listed in this document, except those products referred on items 2, 3 and 12 below.

2. Are exempt from registration medical devices undergoing clinical trials, fulfilled the legal provisions of the health authority responsible for carrying out this activity, being prohibited its marketing and/or use for other purposes.

3. Are exempt of registration new presentations consist in a set of medical devices already registered, and in its individual packaging intact, must contain in the label and / or instructions for use, the information for registration of the corresponding medical devices.

4. ANVISA will grant registration for families of medical devices.

5. When requesting the registration of medical devices classified under Classes II, III and IV, the manufacturers or importers should submit the following documents to ANVISA:

a) Documentary proof of payment of the corresponding sanitary surveillance fee;

b) Information identifying the manufacturer or importer and the medical device as described in Annexes III.A, III.B and III.C of this document, declared and signed by the duly-accredited legal representative and the Technical responsible;

c) Copy of the authorization of the manufacturer or exporter abroad for the importer to retail its medical device in Brazil. When authorized to do so by the exporter and the manufacturer;

d) For imported medical devices, documentary proof of registration or certificate of free trade or equivalent document granted by the competent authority in the countries where the medical device is manufactured and marketed;

e) Proof of compliance with the legal provisions stipulated in the Technical Regulations, pursuant to the ANVISA legislation that regulates medical devices.

6. The manufacturers or importers requesting registration of medical devices classified under Class I should submit the documents listed in Items 5(a), 5(b) and 5(e) to ANVISA.

7. The documentation presented for registration, alteration or revalidation of the registration will be assessed by ANVISA, which will issue its decision through publication in the Federal Government Gazette (DOU – *Diário Oficial da União*).

8. The assessment of the documentation will be undertaken within the legal conditions and periods stipulated in sanitary legislation.

9. In order to request an alteration to the registration of the medical device, the manufacturer or importer should submit al least the documentation stipulated on item 5(a), Annex III.A, completed, together with the other documents required for the original registration of the product whose information has been modified.

10. In order to request the revalidation of the registration of a medical device, the manufacture or importer should submit the documentation stipulated on item 5(a), as so as in Annex III.A completed. This information should be submitted within the period stipulated by the sanitary legislation, which does not stop the marketing until the expiration of its registration.

11. The manufacturer or importer holder of the registration of the medical device may request the cancellation of the registration through submission of Annex III.A completed.

12. Accessories produced by a manufacturer exclusively for joint use with a medical device manufactured and that is already registered are exempt from registration, when the Technical Report (Annex III.C) for the registration of this product contains information on this accessory. Additional accessories may be attached to the original registration, with a detailed explanation of the basis of their functioning, action and content, as stipulated in item 9 of Part 3 of this document.

13. The registration of products for health will remain valid for 5 (five) years, and may be revalidated successively for similar periods.

PART 4 – Compliance to Information

1. Any changes made by the manufacturer or importer, to information listed in this regulation, referred on item 5 of Part 3 of this document should be communicated to ANVISA within 30 (thirty) working days, in accordance with item 9 of Part 3 of this document.

2. Any communication or advertising of medical devices conveyed in the consumer market must keep strict accordance with the information submitted by the manufacturer or importer to ANVISA.

PART 5 - Administrative Sanctions

1. As a health action and in sight of detailed evidence, ANVISA will suspend the registration of medical devices in cases where:

a) is suspended for security reasons duly justified, the validity of any of the documents referred on item 5 of Part 3 of this document;

b) is proven non-compliance with any requirement of Part 4 of this Regulation;

c) the product is under investigation by the competent health authority, concerning to irregularity or defect in the product or manufacturing process, which pose a risk to consumer health, patient, operator or third parties involved, with justification.

2. ANVISA will cancel the registration of medical devices in cases where:

a) be proved the falsity of the information provided in the documents referred on item 5 of Part 3 of this Regulation, or if any of those documents is canceled by ANVISA;

b) Be proved by ANVISA that the product or manufacturing process may present a risk to consumer health, patient, operator or third parties.

3. The suspension of registration of medical devices will be published in the Official Gazette - DOU by ANVISA and will continue until the solution of the problem that caused the penalty. Its nullity will be notified through the Gazette.

4. The cancellation of registration of health products will be published in the Official Gazette by ANVISA.

ANNEX I

DEFINITIONS

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The following definitions apply only to this document, and may have different meaning in another context.

01 - Accessory: Product manufactured solely for the purpose of integrating a medical device, giving to this product a function or feature complementary technique.

02 - Consumer: Person who uses a medical device as final user.

03 - Manufacturer: Any person, who designs, manufactures, assembles or processes in the country a finished medical device, including third parties authorized to sterilize, label and/or package this product.

04 - Family of medical devices: A group of medical devices, where each product has similar technical characteristics, described in items 1.1, 1.2 and 1.3 of Technical Report (Annex III.C).

05 - Instructions for use: Manuals, brochures and other documents accompanying the medical device, containing technical information about the product.

06 - Importer: Legal person, public or private that develops the activity to introduce in the country medical devices manufactured outside of it.

07 - Reusable surgical instrument: instrument for surgical use for cutting, drilling, sawing, milling, shaving, clipping, remove, pinch or perform any other similar procedure, with no connection to any active medical device and that can be reused after being subjected to appropriate procedures.

08 - Batch: A quantity of a medical device drawn into a cycle of manufacturing or sterilization, whose main characteristic is the homogeneity.

09 - Operator: Person who develops professional practice using a medical device.

10 – Body orifice: Any natural opening in the human body, including the eye opening or artificially created as a stoma.

11 - Clinical Research: investigation using human in order to verify the performance, safety and efficacy of a product for health, in the form of health legislation which deals with this issue.

12 - Time: Transitional: Up to 60 minutes of continuous use.
Short term: Up to 30 days of continuous use.

Long term: More than 30 days of continuous use.

13 - Medical device: Product for use in health, such as equipment, apparatus, material, article or system of use in health or implementing medical, dental or laboratory, for prevention, diagnosis, treatment, rehabilitation or contraception, and not using pharmacological, immune or metabolic means to perform their main function to humans, may however be assisted in his duties by such means.

13.1 - Active medical device: Any medical device whose operation depends on the electric power supply or any other power source different from the one generated by the human body or gravity and which works by converting this energy. Are not considered as active medical devices those designed to transmit energy, substances or other elements between an active medical device and the patient, without causing significant change.

13.2 - Active medical device for diagnosis: Any active medical device, whether used alone or in combination with other medical devices, designed to provide information for the detection, diagnosis, monitoring or treatment of physiological conditions or health, disease or congenital deformities.

13.3 - Active medical device for therapy: Any active medical device, whether used alone or in combination with other medical devices, designed to sustain, modify, replace or restore biological functions or structures in the context of treatment or relief of an illness, injury or disability .

13.4 - Medical device for single-use: Any medical device intended to be used in prevention, diagnosis, therapy, rehabilitation or contraception, usable only once, as specified by the manufacturer.

13.5 - Implantable medical device: Any medical device designed to be fully inserted into the human body or to replace an epithelial surface or ocular, by surgical intervention, and intended to remain in place after the intervention. It is also considered an implantable medical device any medical devices designed to be partially introduced into the human body through surgery, and remain after this intervention by long term.

13.6 - Invasive medical device: medical device that penetrates fully or partially within the human body, through a body orifice or through the body surface.

13.7 - Invasive surgical device: invasive medical device that penetrates inside the human body through the body surface through or in connection with a surgical intervention.

14 - Legal representative: a person with sufficient powers to represent a manufacturer or importer, whether because of corporate character or by delegation.

15 - Technical Responsible: Graduated professional, trained in the technologies that compose the product, responsible for the technical information provided by the manufacturer or importer and by the quality, safety and efficacy of the marketed product.

16 - Label: Identification applied directly printed on the packaging of medical device.

17 – Central circulatory system: It includes the following vessels: the pulmonary arteries, ascending aorta, coronary artery, primitive carotid artery, internal carotid artery, external carotid artery, cerebral arteries, brachiocephalic trunk, cardiac veins, pulmonary veins, superior vena cava and inferior vena cava.

18 - Central Nervous System: Includes the brain, cerebellum, medulla and spinal cord.

ANNEX II

CLASSIFICATION

I. Application

1. The application of classification rules shall be governed by the intended purpose of medical devices.

2. If a medical device intended to be used in combination with another medical device, the classification rules are applied to each of the medical devices separately. Accessories are classified by themselves, separately from medical device with which they are used.

3. The technical support (software) that commands a medical device or has influence on their use will fit automatically in the same class.

4. If a medical device is not intended to be used solely or mainly on one specific part of the body, should be considered for classification its more critical use.

5. If to a same medical device are several rules applicable, considering the performance given by the manufacturer, the higher rule will be applied.

6. For purposes of applying this classification of medical devices to legislation approved previous to this document, will be proceeded as follows:
a) Class 1 above corresponds to Class I on this document;
b) Class 2 above corresponds to Class II on this document;
c) Class 3 above corresponds to Class III and IV on this document.

II. Rules

1. Noninvasive Medical Device

Rule 1

All noninvasive medical devices are in class I, except those to which is applicable the rules that follow.

Rule 2

All noninvasive medical devices intended for storage or conduction of blood, body fluids or tissues, liquids or gases intended for infusion, administration or introduction into the body, are in Class II:
a) if they can be connected to an active medical device on class II or in a higher class;

b) if they are intended to conduction, storage or transportation of blood or other body fluids or storing organs, parts of organs or tissues of the body;

in all other cases, belong to Class I.

Rule 3

All noninvasive medical devices intended to alter the chemical or biological blood composition, other body fluids or other liquids intended for introduction into the body are in Class III, except if the treatment consists on filtration, centrifugation or gas exchanges, in this case fall under Class II.

Rule 4

All noninvasive medical device coming into contact with injured skin:
a) fits in Class I if they are intended to be used as a mechanical barrier, for compression or absorption of exudates;
b) fits in Class III if they are intended to be used principally with wounds which have produced dermis rupture and can only heal by secondary intention;

c) fits in Class II in all other cases, including medical devices used primarily to operate on the microenvironment of the wound.

2. Invasive Medical Devices

Rule 5

All invasive medical devices applicable to the body orifices, except for invasive surgical products, which are not intended for connection to an active medical device:
a) are fall under Class I if intended for temporary use;
b) are fall under Class II if intended to short-term use, except if used in the oral cavity into the pharynx, the external auditory canal to the eardrum or the nasal cavity, in these cases fall under Class I;
c) are fall under Class III if intended for long-term use, except when used in the oral cavity into the pharynx, the external auditory canal to the eardrum or the nasal cavity and are not absorbable membrane, these cases are fall under Class II.
All invasive medical devices applicable on body orifices, except the invasive surgical devices, intended for connection to an active medical device class II or in a higher class are fall under Class II.

Rule 6

All invasive surgical devices, for use transitional fits in Class II, except if:

a) are intended specifically to the diagnosis, monitoring and correction of cardiac dysfunction or central circulatory system through direct contact with these body parts, in these cases fits in Class IV;
b) are reusable surgical instruments, these cases fits in Class I;
c) are intended to supply energy in form of ionizing radiation, in which case fits in Class III;
d) is intended to exert biological effect or to be totally or largely absorbed, in these cases fits in Class III;
e) are intended to administer medicines by an infusion system, when proceeded in a potentially dangerous way, considering the application way, in this case fits in Class III.

Rule 7

All invasive surgical products, for use in short term are fall under Class II, except in cases that are intended:
a) specifically to diagnostic, monitoring and correction of cardiac dysfunction or central circulatory system through direct contact with these body parts, these cases fits in Class IV, or

b) specifically for use in direct contact with the central nervous system, in this case fits in Class IV, or
c) to administrate energy in form of ionizing radiation, in this case fits in Class III, or
d) to perform biological effect or to be absorbed, totally or largely, in these cases fits in Class IV, or
e) to undergo chemical changes in the body or to administer medicines, excluding medical devices intended to be placed in the teeth, in this case fits in Class III.

Rule 8

All implantable medical devices and invasive surgical products, for use in long term fits in Class III, except if they are intended:
a) to be placed in the teeth, in this case fall under Class II;
b) to be used in direct contact with the heart, circulatory system or central nervous system, in this case fall under Class IV;
c) to produce a biological effect or to be absorbed, totally or largely, in this case fall under Class IV;
d) to undergo chemical change in the body or administer medicines, unless they are intended to be placed in the teeth, in this cases fits in Class IV.

3. Additional Rules Applicable to Active Medical Device

Rule 9

All active medical devices intended to administer or exchange energy fits in Class II unless their characteristics are such that they can administrate or exchange energy with the human body in a potentially dangerous way, considering the nature, density and place for application of the energy, in this cases fits in Class III.
All active products intended to control or monitor the operation of active medical devices to therapy in Class III or intended to directly influence the functioning of these products are fall under Class III.

Rule 10

The active medical devices for diagnostic or monitoring are in Class II:
a) if they are intended to administrate energy to be absorbed by the human body, except for medical devices whose function is to illuminate the patient's body in the visible spectrum;
b) if they are intended to produce images in-vivo from the distribution of radiopharmaceuticals;
c) if intended to diagnosis or direct monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of

variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS, in this case are fall under Class III.
The active medical devices intended to deliver ionizing radiation for diagnostic radiology or radiation oncologists, including products intended to control or monitor such medicinal products or which directly influence the functioning of these products are fall under Class III.

Rule 11

All active medical devices intended to administer medicines, body fluids or other substances into the body or to remove those fits in Class II, unless this is done in a potentially dangerous way, considering the nature of the substances, the body part involved and the way of application, in this case fall under Class III.

Rule 12

All other active medical devices fall under Class I.

4. Special Rules

Rule 13

All medical devices that incorporate as a part a substance that can be used separately like a drug, and which may exert upon the body a complementary action to these products fall under Class IV.

Rule 14

All medical devices used for contraception or for prevention of transmission of sexually transmitted diseases are fall under Class III, unless the products are implantable medical devices or invasive medical devices for long-term use, in this case fits in class IV.

Rule 15

All medical devices intended specifically for disinfecting, cleaning, washing and, when appropriate, hydrating contact lenses, fits in Class III.
All medical devices specifically designed to disinfect other medical devices fits in Class II.
This rule does not apply to products intended to cleaning medical devices, other than contact lenses, through physical action.

Rule 16

The non-active medical devices designed specifically for registration of radiographic images for diagnosis, fits in Class II.

Rule 17

All medical devices that use animal tissues or inert derivatives, fits in Class IV, unless these products are only intended to come into contact with the skin intact.

Rule 18

Notwithstanding the other rules, blood bags fall under Class III.

ANNEX III.A

> FORM THE MANUFACTURER OR IMPORTER OF MEDICAL DEVICES (format PDF)

ANNEX III.B

INFORMATION ON LABELING AND INSTRUCTIONS FOR USE OF MEDICAL DEVICE

1. General Requirements

1.1. The information described on the label and on instructions for use must be written in Portuguese language.

1.2. All medical devices must include in their packaging the instructions for use. Exceptionally, these instructions may not be included in the packaging of the products those fits in classes I and II, provided that the safety of use of these products can be guaranteed without such instructions.

1.3. The information necessary for the proper and safe use of medical devices must, where possible and appropriate, be present in the product itself and / or label of its individual package, or in the impossibility of this, in the label of its commercial packaging. If is not possible to wrap each individual unit, such information should be in the operating instructions that accompany one or more medical devices.

1.4. When appropriate, information can be presented in the form of symbols and colors. The symbols and colors of identification used must comply with regulations or technical standards. If there are no regulations or rules, the symbols and colors should be described in the documentation that accompanies the medical device.

1.5. If in a specific technical regulation of medical devices, there is a need for further information, because of the uniqueness of the product, they shall be incorporated into the label or instructions for use, as applicable.

2. Labels

The model of label shall contain the following information:

2.1 The name and address of manufacturer and importer, as appropriate.

2.2 The strictly necessary information for the User to identify the medical device and the content of its packaging;

2.3 Where applicable, the word "Sterile";

2.4 The batch code, preceded by the word "batch", or the serial number, as appropriate;

2.5 As applicable, date of manufacture and expiry date or the date before which should the medical device be used, to have full security;

2.6 Where applicable, indication that the medical device is for single use;

2.7 The special conditions of storage, conservation and/or manipulation of the medical device;

2.8 The instructions for use of medical device;

2.9 All warnings and/or precautions to be taken;

2:10 Where applicable, the method of sterilization;

2:11 Name of the technical responsible enabled to the function;

2:12 Registration number of the medical device, preceded by the acronym of ANVISA.

3. Instructions for use

The model of the instructions for use should contain the following information, as applicable:

3.1 The information referred on item 2 of this Annex (label), except those contained in paragraphs 2.4 and 2.5;

3.2 The expected performance in the General Requirements of ANVISA which regulates the Essential Requirements of Safety and Efficacy of Medical devices, as well as any secondary adverse reactions;

3.3 In case of medical device that should be installed or connected to other products to function, according to its intended purpose, must be provided enough details about its characteristics to identify the products that can be used with this device, in order to obtain a safe combination;

3.4 All information that allows to testify whether a medical device is well installed and can function properly and safely, as well as information concerning to the nature and frequency of maintenance operations and calibration, to be performed to ensure the continued good operation and safety of the product;

3.5 Information to avoid certain risks of deployment of medical devices;

3.6 Information regarding the risks of reciprocal interference posed by the presence of medical devices in specific investigations or treatment;

3.7 The necessary instructions in case of damage to protective packaging of the sterility of a sterile medical device, and, when applicable, the details of appropriate methods of sterilization;

3.8 In case of the medical device is reusable, information on proper procedures for reuse, including cleaning, disinfection, storage and, when appropriate, the sterilization method, if the product has to be re-sterilized, and any restrictions on the number of possible reuses.

If the medical device must be sterilized before use, the instructions for cleaning and sterilization must be presented so that, if properly made, the product meets the requirements in the

General Regulatory Requirements by ANVISA which deals with the Essential Requirements for safety and efficacy of products for health;

3.9 Information about additional treatment or procedure that must be done before using the product (for example, sterilization or final assembly, among others).

3:10 If a medical device deliver radiation for medical purposes, the information concerning the nature, type, intensity and distribution of this radiation should be described.

The instructions should include details allowing the medical staff to inform the patient about the contraindications and precautions. Such information shall include, specifically:

3:11 precautions to take in case of changes in the performance of the medical device;

3:12 precautions to take regarding the exposure, in reasonably foreseeable environmental conditions to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration and thermal ignition sources, among others;

3:13 Adequate information on the drugs(s) that the medical device is designed to administer, including any restrictions on choice of those substances;

3:14 precautions to take if the product presents a specific unpredictable risk associated with its disposal;

3.15 The drugs incorporated into the medical device as part of it, according to item 7.3 of the regulations from ANVISA which deals with the Essential Requirements for safety and efficacy of products for health;

3.16 The level of accuracy attributed to medical devices for measurement.

ANNEX III C

TECHNICAL REPORT

1. The technical report should contain the following information:

1.1. Detailed description of the medical device, including the fundamentals of their operation and their actions, their content or composition when applicable, and list of accessories to integrate the product;

1.2. Indication, purpose or use for which the medical device is intended, as indicated by the manufacturer;

1.3. Precautions, restrictions, warnings, special cautions and clarifications on the use of medical devices, as well as storage and transport;

1.4. Presentations of medical devices;

1.5. Flowchart containing the steps of the manufacturing process of the medical device, with a brief description of each step of the process, until the finished product;

1.6. Description of the efficacy and safety of medical devices in accordance with the regulations of ANVISA which treats about the Essential Requirements of Efficacy and Safety of Medical devices. In case of the description do not prove the efficacy and safety of the product, ANVISA will request clinical research for the product.

2. In the case of registration of medical devices those fits in Class I, Technical Report must contain the information specified in item 1.1 to 1.4 of this Annex.