

RESOLUTION RDC NO. 185, OF OCTOBER 22ND, 2001

Approves the Technical Regulation presented in the herein Annex about the registration of medical products at ANVISA, as well as its alteration, revalidation, or cancellation.

The Collegiate Board of Director of the Brazilian National Health Surveillance Agency (ANVISA), in the exercise of the powers vested by Article 11, subsection IV, of ANVISA Regulation approved by Decree no. 3,029, of April 16th, 1999, in meeting held on October 10th, 2001,

considering the need to update the procedures for the registration of healthcare products, addressed by Law no. 6,360, of September 23rd, 1976; by Decree no. 79,094, of January 5th, 1977; and by SVS/SAS Ordinance no. 01, of January 23rd, 1996;

considering the need to incorporate Mercosur Resolution GMC no. 40/00, which addresses the registration of medical products;

hereby adopts this Resolution and I, Director-President, determine its publication.

Article 1. To approve the Technical Regulation presented in the herein Annex about the registration of medical products at the Brazilian National Health Surveillance Agency (ANVISA), as well as its alteration, revalidation, and cancellation.

Sole Paragraph. Other healthcare products, defined as “*correlatos*”¹ by Law no. 6,360/76 and by Decree no. 79,094/77, are deemed as medical products for the purpose of the herein Resolution, excluding the reagents for in-vitro diagnostic use.

Article 2. Manufacturers or importers of a medical product shall submit to ANVISA the documents required for its registration, alteration, revalidation, or cancellation of such, and listed in items 5, 6, 9, 10, and 11 of Part 3 of the herein attached Regulation.

Paragraph 1. Besides being submitted physically printed, the following information, expected to be included in the documents addressed in this Article, shall be submitted electronically in order to be available on ANVISA website:

- a) Data of the manufacturer or importer and data of the product, indicated in the form available on Annex III.A of this Technical Regulation;
- b) Labels and instructions for use, described in Annex III.B of this Technical Regulation.

Article 3. According to the provisions of Law no. 6,360/76 and of Decree no. 79,094/77, manufacturers or importers of medical products that are exempt from *registro* and are

¹ According to Decree no. 79,094/77, “Produtos correlatos” are healthcare equipment and materials used to protect and maintain individual or collective health, i.e., for translation purposes, the term is interchangeably used with “healthcare products”. [T.N.]

included in lists elaborated by ANVISA shall apply for a *cadastro* at the Agency, submitting the payment proof of the corresponding health surveillance fee and the information set forth in Article 2, Paragraph 1, of this Resolution.

Sole Paragraph. The alteration, revalidation, or cancellation of the *cadastro* of the product addressed in the caput shall adopt the same procedures set forth in items 9, 10, 11, and 13 of Part 3 of the herein Annex, being also subject to the provisions of Parts 4 and 5 of this Regulation.

Article 4. In case of medical equipment, manufacturers or importers shall indelibly affix at least the following labeling information on a visible location of the equipment's external part:

- a) identification of the manufacturer (name or brand);
- b) identification of the equipment (commercial name and model);
- c) serial number of the equipment;
- d) number of the registration of the equipment at ANVISA.

Article 5. The application for the revalidation of a medical product registration filed after the date of the publication of this Resolution shall adjust the information of the original process to the provisions set forth herein and to the prescriptions of the technical regulation specific to the product, published while its registration remained in force.

Article 6. The petitions for registration, its exemption, alteration, revalidation, or cancellation filed at ANVISA before the publication of this Resolution are hereby subject to the provisions of SVS/SAS Ordinance no. 1/96 and SVS Ordinance no. 543/97.

Article 7. This Resolution shall come into force on the date of its publication.

Article 8. SVS/SAS Ordinance no. 1, of January 23rd, 1996, and SVS Ordinance 543, of October 29th, 1997, are hereby revoked.

GONZALO VECINA NETO

ANNEX

TECHNICAL REGULATION

REGISTRATION OF MEDICAL PRODUCTS, ITS ALTERATION, REVALIDATION, OR CANCELLATION

PART 1 – Scope and Definitions

1. The provisions of this document shall apply to manufacturers and importers of medical products.

2. For the purposes of registration, the classification, the procedures, and the specifications described in this document shall apply to medical products and their accessories, as defined in Annex I.
3. The definitions herein established on Annex I shall be adopted for the purposes of this document.
4. This document shall not be applicable to used or reconditioned medical products.

PART 2 – Classification

1. The medical products subject of this document shall be classified as Class I, II, III, or IV, according to the intensive risk they represent to the health of consumers, patients, operators, or third parties involved. To classify medical products, the classification rules herein described in Annex II shall be applied.
2. In case of doubts in the classification after applying the rules described in Annex II, Anvisa shall be liable for classifying the medical product.
3. The classification rules herein described in Annex II may be updated according to the administrative procedures adopted by Anvisa, taking into consideration the technological progress and the information on the adverse effects caused by the use or application of a medical product.

PART 3 – Procedures for Registration

1. The registration of every medical product indicated in this document is hereby mandatory, except for those referred hereafter in items 2, 3, and 12.
2. Medical products submitted to clinical research are hereby exempt from registration, provided that they comply with the legal provisions of the competent health surveillance authority on the performance of this activity, prohibiting such products to be commercialized and used for other purposes.
3. New presentations of a medical product set already registered and in intact individual packaging are hereby exempt from registration, provided that its label and instructions for use contains the information about the registration of the corresponding medical products.
4. Anvisa shall grant the registration of families of medical products.
5. To apply for the registration of families of medical products classified as class II, III, or IV, manufacturers or importers shall submit to Anvisa the following documents:
 - a) Payment proof of the corresponding health surveillance fee;

b) Information to identify the manufacturer or importer and their medical product, described in herein Annexes III.A, III.B, and III.C, stated, and signed by their legal representative and technical manager;

c) Copy of the authorization given by the manufacturer or exporter overseas so the importer may commercialize the medical product in Brazil. When authorized by the exporter, the importer shall demonstrate the commercial relationship between the manufacturer and the exporter;

d) For imported medical products, proof of registration or free sale certificate (or equivalent document), granted by the competent authority in the countries where the medical product is manufactured and commercialized;

e) Proof of compliance with legal provisions set forth in technical regulations, such as Anvisa Legislation that regulates medical products.

6. Manufacturers or importers that request the registration of medical products classified as class I shall submit to Anvisa the documents indicated in the aforementioned items 5(a), 5(b), and 5(e).

7. Anvisa shall evaluate the documentation submitted for *registro*, its alteration, or revalidation and shall publish its decision on the Brazilian Official Gazette (DOU).

8. The evaluation of the documentation shall be carried out within legal conditions and periods set forth in health surveillance legislation.

9. To request the alteration of a medical product registration, manufacturers or importers shall submit, at least, the document required in item 5(a), Annex III.A completed, and other documents required for the original registration of the product whose information has been modified.

10. To apply for the revalidation of a medical product registration, manufacturers or importers shall submit the document required in item 5(a) and the completed Annex III.A. This information shall be submitted within the period set forth in health surveillance legislation and the commercialization of such product shall not be interrupted until the expiration date of its registration.

11. When medical product registration holders, manufacturers or importers may request the cancellation of the registration by submitting the completed Annex III.A.

12. Accessories are hereby exempt from registration as long as they are exclusively manufactured to be part of a medical product with a registration whose technical report (Annex III.C) has information on such accessories. The medical product and its accessories shall have the same manufacturer. New accessories may be attached to the original registration by detailing the principles of their operation, actions, and content, as set forth in item 9 of this Part 3.

13. The registration of healthcare products shall be valid for five years, after which it may be successively revalidated for the same period of time.

PART 4 – Compliance with Information

1. Any change made by manufacturers or importers in the information herein requested in item 5 of Part 3 shall be communicated within 30 days for Anvisa's approval, in accordance with the provisions of item 9 of Part 3.
2. Every announcement or publicity of medical products made in the consumption market shall strictly match the information submitted to Anvisa by their manufacturer or importer.

PART 5 – Administrative Penalties

1. As a health surveillance measure and when seeking well-grounded reasons, Anvisa shall suspend the registration of medical products in the following cases:
 - a) when the validity of any document herein addressed in item 5 of Part 3 is suspended for safety reasons and is duly justified;
 - b) when the non-compliance with any requirement herein made in Part 4 has been proven;
 - c) when the product is being investigated by the competent health surveillance authority due to irregularities or defects found in the product or in its manufacturing process, representing a risk to the health of consumers, patients, operators, or third parties involved.
2. Anvisa shall cancel the registration of medical products in the following cases:
 - a) when there is proof that the information in any document herein referred in item 5 of Part 3 has been forged or when any of these documents has been cancelled by Anvisa;
 - b) when the product or its manufacturing process has been proven by Anvisa to be a risk to the health of consumers, patients, operators, or third parties involved.
3. The suspension of medical product registrations shall be published on the Brazilian Official Gazette (DOU) by Anvisa and shall last until the solution to the problem that originated the penalty has been communicated on the DOU.
4. The cancellation of medical product registrations shall be published on the DOU by Anvisa.

ANNEX I

DEFINITIONS

The following definitions are solely applicable to this document and may have different meanings in other contexts:

1. Accessory: product exclusively manufactured to be part of a medical product, providing to this product a complementary technical characteristic or function.

2. Consumer: physical person who is the final medical product user.
3. Manufacturer: any person that designs, manufactures, assembles, or processes a finished medical product in the country, including third parties authorized to sterilize, label or package this product.
4. Medical product family: set of medical products within which each product has the similar technical characteristics herein described in items 1.1, 1.2, and 1.3 of Technical Report (Annex III.C).
5. Instructions for use: manuals, brochures, and other documents that come along with the medical product and contain technical information on the product.
6. Importer: legal person, public or private, that executes the activity of bringing to the country a medical product manufactured overseas.
7. Reusable surgical instrument: instrument intended for surgical use for cutting, wearing, sawing, milling, scraping, stapling, removing, clamping, or any other similar procedure, with no connection to any active medical product, and that may be reused after submitted to appropriate procedures.
8. Batch: quantity of a medical product resulting from a manufacturing or sterilization cycle, the essential characteristic of which is homogeneity.
9. Operator: person whose professional activity is performed by using a medical product.
10. Body orifice: Any natural human body opening, including the eye socket or any artificial opening, such as a stoma.
11. Clinical research: investigation using human beings, intended to verify the performance, safety, and efficacy of a healthcare product, in view of the health surveillance legislation about this matter.
12. Term: transient: 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 product: healthcare product, such as equipment, devices, materials, articles, or systems for medical, odontological, or laboratory use or application, intended for prevention, diagnosis, treatment, rehabilitation, or anti-conception and that does not use pharmacological, immunological, or metabolic means to fulfill its main function in human beings, but can have its functions assisted by such means.
- 13.1. Active medical product: any medical product, the operation of which depends on an electrical energy source or any power source different from that generated by human body or gravity and that works due to the conversion of such energy. Medical products intended to transmit energy, substances or other elements between the patient and an active medical product without resulting in any significant change are not considered active medical products.

13.2. Active diagnostic medical product: any active medical product used alone or in combination with other medical products, intended to provide information for detection, diagnosis, monitoring, or treatment of physiological or health conditions, diseases, or congenital disorders.

13.3. Active therapeutic medical product: any active medical product used alone or in combination with other medical products, intended to support, modify, substitute, or restore biological functions or structures for the treatment or relief of a disease, injury, or disorder.

13.4. Single-use medical product: any medical product intended to be used only one time for prevention, diagnosis, therapy, rehabilitation, or anti-conception, as specified by the manufacturer.

13.5. Implantable medical product: any medical product designed to be fully inserted into the human body or to substitute an epithelial or ocular surface by surgical intervention and intended to remain in site afterwards. Any medical product intended to be partially inserted into the human body by a surgical intervention and to remain in site long term is also deemed as an implantable medical product.

13.6. Invasive medical product: medical product fully or partially inserted into the human body, be it by a body orifice or through the body surface.

13.7. Surgically invasive medical product: an invasive medical product inserted into the human body through the body surface by a surgical intervention or during one.

14. Legal representative: physical person with enough powers to represent a manufacturer or importer due to an authorization of a business representation or to delegation.

15. Technical manager: professional with a university degree, with knowledge of the technologies that compose the product, responsible for the technical information submitted by the manufacturer or importer to ensure the product's quality, safety, and efficacy.

16. Label: printed identification directly applied to the packaging of the medical product.

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

18. Central nervous system: this includes the brain, cerebellum, medulla oblongata, and spinal cord.

ANNEX II

CLASSIFICATION

I. Application

1. The classification rules shall be applied according to the intended use of the medical product.
2. Should a medical product be intended to be used in combination with another medical product, the classification rules shall be applied to each product separately. The accessories shall be classified for themselves, separately from the medical products with which they are used.
3. Logical supports (software) that command a medical product or influence its use shall be automatically classified within the same class.
4. If a medical product is not intended to be exclusively or mainly used in a specific body part, its most critical use shall be considered for its classification.
5. Should several rules be applicable to the same medical product, the rules corresponding to the highest classification shall be applied taking into account the performance intended by the manufacturer.
6. In order to apply this new medical product classification to the legislation previously in force, the correspondence shall function as follows:
 - a) Previous class 1 herein corresponds to class I;
 - b) Previous class 2 herein corresponds to class II;
 - c) Previous class 3 herein corresponds to classes III and IV.

II. Rules

1. Non-invasive medical products

Rule 1

All non-invasive medical products shall be classified as class I, except those to which the following rules are applicable.

Rule 2

All non-invasive medical products intended for storage or conduction of blood, body tissues or fluids, liquids, or gases intended for perfusion, administration or insertion into the body shall be classified as class II if:

- a) they can be connected to an active medical product of class II or higher class;
- b) they are intended for conduction, storage, or transportation of blood or other body fluids, or for transportation of organs, parts of organs, or body tissues;

in all other cases, the product shall be deemed as class I.

Rule 3

All non-invasive medical products intended to alter the chemical or biological composition of the blood, other body fluids, or other liquids intended to be inserted into the body shall be classified as class III, except if the treatment consists of filtration, centrifugation, or changes of air or heat, when the product is deemed as class II.

Rule 4

All non-invasive medical products that may come into contact with injured skin shall be classified as:

- a) class I if intended to be used as a mechanical barrier for the compression or absorption of exudates;
- b) class III if intended to be mainly used in wounds that resulted in dermis rupture and that can be only healed by secondary intention.
- c) class II in all other cases, including medical products intended to mainly act in the micro-surroundings of a wound.

2. Invasive medical products

Rule 5

Except for surgically invasive medical products, all invasive medical products applicable to body orifices and not intended to be used in combination with another medical product shall be classified as:

- a) class I if intended for transient use;
- b) class II if intended for short-term use, except if used in the oral cavity until the pharynx, in the external auditory canal until the eardrum, or in the nasal cavity, when they are deemed as class I;
- c) class III if intended for long-term use, except if used in the oral cavity until the pharynx, in the external auditory canal until the eardrum, or in the nasal cavity and are not absorbed by the mucous membrane, when they are deemed as class II.

Except for surgically invasive medical products, all invasive medical products applicable to body orifices and intended to be used in combination with active medical products of class II or higher classes shall be classified as class II.

Rule 6

All surgically invasive medical products of transient use shall be classified as class II, except if:

- a) they are specifically intended for diagnosis, monitoring, or correction of cardiac dysfunction or of dysfunctions in the central circulatory system by having direct contact with these body parts, when they are deemed as class IV;

- b) they are reusable surgical instruments, when they are deemed as class I;
- c) they are intended to supply energy in the way of ionizing radiation, when they are deemed as class III;
- d) they are intended to have a biological effect or to be fully or mostly absorbed, when they are deemed as class III;
- e) they are intended for the administration of medications by using an infusion system, when potentially dangerously performed considering the application method, when they are deemed as class III.

Rule 7

All surgically invasive medical products of short-term use shall be classified as class II, except in cases they are intended:

- a) to be specifically used in diagnosis, monitoring, or correction of cardiac dysfunction or of dysfunctions in the central circulatory system by having direct contact with these body parts, when they are deemed as class IV;
- b) to be specifically used in direct contact with the central nervous system, when they are deemed as class IV;
- c) to supply energy in the way of ionizing radiation, when they are deemed as class III;
- d) to have a biological effect or to be fully or mostly absorbed, when they are deemed as class IV;
- e) to suffer chemical alterations in the organism or when administering medications, when they are deemed as class III, except those medical products intended to be placed in the teeth.

Rule 8

All implantable and all surgically invasive medical products of long-term use shall be classified as class III, except in cases they are intended:

- a) to be placed in the teeth, when they are deemed as class II;
- b) to be used in direct contact with the heart, central nervous or central circulatory systems, when they are deemed as class IV;
- c) to have a biological effect or to be fully or mostly absorbed, when they are deemed as class IV;
- d) to suffer chemical alterations in the organism or when administering medications, when they are deemed as class IV, unless if medical products intended to be placed in the teeth.

3. Additional Rules Applicable to Active Medical Products

Rule 9

All active therapeutic medical products intended to administer or change energy shall be classified as class II, except if their characteristics are such that this administration and change with the human body may be potentially dangerous, considering the nature, density, and the site of energy application, when they are deemed as class III.

All active products intended to control or monitor the operation of active therapeutic medical products classified as class III or intended to directly influence these products' operation shall be classified as class III.

Rule 10

Active medical products intended for diagnosis or monitoring shall be classified as class II if:

- a) they are intended to administer energy to be absorbed by the human body, except those medical products whose function is to light up the patient's body in the visible spectrum;
- b) they are intended to provide in-vivo imaging of the distribution of radiopharmaceuticals;
- c) they are intended for the monitoring or direct diagnosis of vital physiological processes, unless they are specifically intended to monitor vital physiological parameters, the variations of which may result in immediate risk to the patient's life, such as variations in cardiac functioning, in breathing, or in central nervous system activities, when they are deemed as class III.

All active medical products intended to emit ionizing radiation for radiodiagnostic or radiotherapeutic purposes, including those intended to control or monitor such medical products or to directly influence these products' operation, shall be classified as class III.

Rule 11

All active medical products intended to administer medications, body fluids, or other substances into the organism or to remove these from it shall be classified as class II, unless this activity is potentially dangerously performed, considering the substance nature, the body part involved, and the application method, when they are deemed as class III.

Rule 12

All other active medical products shall be classified as class I.

4. Special Rules**Rule 13**

All medical products that incorporate as their part a substance that, if used separately, may be considered as a medication and may perform upon the human body a complementary action to that of those products incorporated shall be classified as class IV.

Rule 14

All medical products used in contraception or in the prevention of sexually transmissible diseases shall be classified as class III, unless they are implantable or invasive medical products of long-term use, when they are deemed as class IV.

Rule 15

All medical products specifically intended to disinfect, clean, wash, and, if applicable, hydrate contact lenses shall be classified as class III.

All medical products specifically intended to disinfect other medical products shall be classified as class II.

This rule is not applicable to products intended to clean medical products other than contact lenses by using physical action.

Rule 16

All non-active medical products specifically intended to record radiological diagnostic imaging shall be classified as class II.

a) Current class I corresponds to previous class I.

Rule 17

All medical products that use tissues of animal origin or their inert derivatives shall be classified as class IV, except when such products are solely intended to come into contact with intact skin.

Rule 18

Notwithstanding the provisions set forth in the aforementioned rules, blood bags shall be classified as class III.

ANNEX III.A
FORM FOR MANUFACTURERS OR IMPORTERS OF MEDICAL PRODUCTS

1. Identification of the process

- () 1.1. *Registro* of the product () 1.2. *Cadastro* of the product
() 1.3. Alteration () 1.4. Revalidation
() 1.5. Cancellation

Number of the product's registration in the Ministry of Health (in cases 1.3, 1.4, or 1.5):

2. Data of the manufacturer or importer

- 2.1. Company name:
2.2. Commercial name:
2.3.: Address:
2.4. City: 2.5. State: 2.6. Zip code:
2.7. Phone number:
2.8. Fax:
2.9. Email:
2.10. Anvisa Operating Permit (AFE):

3. Data of the product

3.1. Technical identification of the product

Technical name:

Identification code (according to the Codification and Nomenclature of Medical Devices):

Code NCM (according to the Nomenclature of Common Goods):

3.2. Commercial identification of the product

Commercial name of the product:

Commercial model of the product (in case of a product family, fill out this field for each product model):

3.3. Risk classification of the product

Classification rule:

Class of the product:

3.4. Origin of the product

Brazil () International ()

Manufacturer:

Country of manufacture:

Distributor:

Country of origin of the product:

4. Statement of legal representative and technical manager

I hereby declare that the above information is true to the best of my knowledge and belief and may be proven by documents located in the company.

Name of the legal representative:

Job position:

Signature:

Name of the technical manager:

Job position:

Signature:

ANNEX III.B

INFORMATION OF LABELS AND INSTRUCTIONS FOR USE OF MEDICAL PRODUCTS

1. General Requirements

1.1. The information indicated on labels and in instructions for use shall be written in Portuguese.

1.2. All medical products shall include instructions for use inside their packaging. Exceptionally, these instructions may not be included in the packaging of products classified as class I and II, as long as the safety of these products may be secured without such instructions.

1.3. The necessary information for a correct and safe use of the medical product shall be displayed, if possible and adequate, on the product itself or on the label of its individual packaging, or, if not viable, on the label of the commercial packaging. Should it be not possible to package each unit separately, this information shall be provided in the instructions for use that come along one or more medical products.

1.4. When appropriate, the information may be presented by using symbols or colors. Symbols and colors used for identification shall be in compliance with technical regulations or standards. If these do not exist, the symbols and colors used shall be described in the documentation that comes along with the medical product.

1.5. Should a specific technical regulation of a medical product require complementary information due to the specificity of the product, this shall be provided on the label or instructions for use, as applicable.

2. Labels

Label models shall contain the following information:

- 2.1. Company name and address of the manufacturer and importer, as applicable.
- 2.2. Information strictly necessary so the user can identify the medical product and the contents of its packaging.
- 2.3. When applicable, the word “*Estéril*” [“Sterile”].
- 2.4. Batch number, preceded by the word “*Lote*” [“Batch”], or serial number, as applicable.
- 2.5. As applicable, date of manufacture and expiration date or date before which the medical product must be used in order to secure perfect safety.
- 2.6. When applicable, the indication that the medical product is for single use.
- 2.7. Special conditions for storage, preservation and handling of the medical product.
- 2.8. Instructions for use of the medical product.
- 2.9. All warnings and precautions that must be taken.
- 2.10. When applicable, the sterilization method.
- 2.11. Name of the technical manager legally licensed for his/her job position.
- 2.12. Number of the registration of the medical product, preceded by Anvisa’s identification acronym.

3. Instructions for Use

Models of instructions for use shall have the following information, when applicable:

- 3.1. All the information herein indicated in item 2 of this annex (Label), except that of subsections 2.4 and 2.5.
- 3.2. The intended performance described in the General Requirements of the Anvisa Regulation that makes provisions on the Essential Requirements for Safety and Efficacy of Medical Products, as well as any eventual and undesirable secondary effects.
- 3.3. Should a medical product require to be installed or connected to other products to operate according to its intended purpose, sufficiently detailed information on its characteristics shall be provided in order to identify the products with which it may be used so a safe combination may be obtained.
- 3.4. All information that enables to evidence that a medical product has been properly installed and can correctly and safely operate, as well as the information with regard to the nature and frequency of maintenance and calibration activities to be performed in order to ensure permanent and safe operation.

3.5. Useful information to avoid certain risks caused by the implantation of the medical product.

3.6. Information regarding the risks of reciprocal interference derived from the presence of the medical product in specific treatments or investigations.

3.7. Necessary instructions in case of damage to the protective sterile packaging and, when applicable, the indication of adequate re-sterilization methods.

3.8. Should the medical product be reusable, information on the appropriate procedures for its reuse, including those for cleanliness, disinfection, storage and, when applicable, the sterilization method if the product has to be re-sterilized, and any restriction on the possible number of re-sterilizations.

Should the medical product require to be sterilized before use, the instructions related to its cleanliness and sterilization shall be provided in a way that, if correctly followed, the product will meet the general requirements set forth in the Anvisa Regulation that makes provisions on the Essential Requirements for Safety and Efficacy of Medical Products.

3.9. Information on additional procedures or treatments to be carried out before the use of the medical product (for instance, sterilization or final assembly, among others).

3.10. Should a medical product emit radiation for medical purposes, the information related to the nature, type, intensity, and distribution of such emission shall be described.

Instructions for use shall include information that allows medical personnel to inform the patient about contraindications and precautions. This information shall specifically include:

3.11. The precautions to be taken in case of change in the operation of the medical product.

3.12. The precautions to be taken in case the medical product is exposed, under reasonably foreseeable environmental conditions, to magnetic fields, external electric influences, electrostatic discharges, pressure and variations in pressure, acceleration, thermal ignition sources, among others.

3.13. Adequate information on the medication(s) the medical product is intended to administer, including any restriction on the choice of substances to be delivered.

3.14. The precautions to be taken in case the medical product presents an unpredictable specific risk associated to its disposal.

3.15. The medications incorporated as part of the medical product, according to item 7.3 of the Anvisa Regulation that makes provisions on Essential Requirements for Safety and Efficacy of Healthcare Products.

3.16. The degree of accuracy claimed for measuring medical products.

ANNEX III.C

TECHNICAL REPORT

1. Technical reports shall contain the following information:

1.1. Detailed description of the medical product, including the principles of its operation, action, contents, or composition, and – when applicable – the list of accessories intended to be part of the product.

1.2. Indications and intended use of the medical product, as indicated by the manufacturer.

1.3. Precautions, restrictions, warnings, special cautions, and clarifications about the use of the medical product and about its storage and transportation conditions.

1.4. Presentation forms of the medical product.

1.5. Flowchart indicating all the manufacturing stages of the medical product, up to and including the obtention of the finished product, along with a brief description of each stage of the process.

1.6. Description of the efficacy and safety of the medical product in accordance with Anvisa regulations, which make provisions on the Essential Requirements for Efficacy and Safety of Medical Products.

2. If the medical product has been classified as class I, its Technical Report shall contain the information herein required from item 1.1 to 1.4 of this Annex.

3. The legal representative and the technical manager of the establishment are hereby liable for the information presented in this Technical Report and shall indicate their names, job position or professional license, and signatures.

Correction:

Published on the Brazilian Official Gazette (DOU); Executive Power, November 6th, 2001. Republished to correct mistakes in the original, DOU no. 204, of October 24th, 2001, Section 1, page 54.

