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## **National Administration of Drugs, Food and Medical Technology**

### **PUBLIC HEALTH**

Provision 2318/2002 (1285/2004 Arrangement as revised text)

Approves the revised text of the "Mercosur Technical Regulations for the Registration of Medicinal Products" that was approved by Provision N ° 2318/2002.

Buenos Aires, 01/03/2004

Having regard to the Procedure No. 1-47-5172-02-1 the registration of the National Administration of Drugs, Food and Medical Technology and

### **WHEREAS:**

That ANMAT No. 2318/02, is incorporated into national law the text of the GMC Resolution No. 40/00 "MERCOSUR Technical Regulations for the Registration of Medicinal Products."

That the Director of Medical Technology informs fs. 45, on several material errors committed in the transcription of the text of that law.

That these errors are considered correctable under the terms of the regulated by Article 101 of the Administrative Procedures Regulation approved by Decree N ° 1759/72 (TO 1991).

That the Director of Medical Technology and the Directorate of Legal Affairs have taken the intervention of his competition.

To be acting under the powers conferred by Decrees No. 1490/92 and 197/02.

Therefore;

**THE AUDITOR OF THE NATIONAL DRUG ADMINISTRATION, FOOD AND MEDICAL TECHNOLOGY AVAILABLE:**

Clause 1 - Incorporáranse Articles 3.13, 3.14, 3.15 and 3.16 of Annex III.B and III.C Annex GMC Resolution No. 40/00 "MERCOSUR Technical Regulations for the Registration of Medicinal Products" to the N ANMAT ° 2318 of May 23, 2002.



Clause 2 - Approve the revised text of "Mercosur Technical Regulations for the Registration of Medicinal Products" that was approved by ANMAT N ° 2318/02 as amended by this, as Annex I, which will be titled: "Regulation Registration Mercosur Technical Medical Products. ANMAT N ° 2318/02. TO 2004 ", part of this provision.

Clause 3 - Contact the MERCOSUR Administrative Secretariat based in the City of Montevideo, to the knowledge of the States Parties, through the National Section of the Mercosur Common Market Group.

Clause 4 - Register, please contact CACID, Cadi, CADIEM, CADIME, CAEHFA, Fall, CAPA, CAPEMVeL, CAPGEN, CAPROFAC, CILFA, COOPERALA and FAIC. Give to the National Official Register for publication. Give a copy to the Registration Department, the Directorate of Medical Technology and the Department of Institutional Relations. Fulfilled, filed (PERMANENT). - Manuel R. Limeres.

#### ANNEX I

MERCOSUR / GMC / RES. N ° 40/00

MERCOSUR Technical Regulation REGISTRATION OF MEDICAL PRODUCTS (GMC Repeal of Resolution No. 37/96)

WHEREAS: the Treaty of Asuncion, the Protocol of Ouro Preto, Resolutions No. 91/93, 37/96, 152/96, 38/98 and 72/98 of the Common Market Group and Recommendation N ° 13/99 of SWGN ° 11 "Health."

WHEREAS:

It is necessary to update the criteria for Registration of Medicinal Products.

The Common Market Group

RESOLVED:

Article 1 - To approve the "MERCOSUR Technical Regulation Registration of Medicinal Products (Repeal of Resolution No. 37/96 GMC), which is annexed and forms part of this resolution.

Section 2 - States Parties shall bring into force the laws, regulations and administrative provisions necessary to comply with this resolution through the following organizations:

Argentina: ANMAT (National Administration of Drugs, Food and Medical Technology)

Brazil: ANVISA (National Agency of Health Surveillance do Ministério da Saúde)

Paraguay: Ministry of Public Health and Social Welfare

Uruguay: Ministry of Public Health



Section 3 - Entering into force of this resolution is repealed GMC Resolution No. 37/96.

Article 4 - This Resolution shall apply to the territory of States Parties, including trade and extra-zone imports.

Article 5 - States Parties of MERCOSUR should incorporate this resolution to their national legislation by 1 January 2001.

XXXVIII GMC - Buenos Aires, 28/VI/00

## MERCOSUR Technical Regulation REGISTRATION OF MEDICAL PRODUCTS

(Repeal of Resolution No. 37/96 GMC)

### PART 1 - SCOPE AND DEFINITIONS

1. Manufacturers and importers of medical products of the States Parties of MERCOSUR must comply with the provisions of this document.
2. The classification, procedures and specifications described in this document, for the purposes of registration, apply to medical products and accessories as defined in Annex I.
3. For purposes of this document are adopted the definitions provided in Annex I.
4. This document is not applicable to medical products used or reconditioned.

### PART 2 - CLASSIFICATION

1. Medical products, the subject of this document are framed according to the inherent risk they pose to consumer health, patient, operator, or others involved in Class I, II, III or IV. In the framework of the medical product in one of those classes must be applied the classification rules described in Annex II of this document.
2. In case of doubt in the classification resulting from the application of the rules described in Annex II shall be allocated to the competent health authority the framework of the medical product.
3. The classification rules described in Annex II of this document may be updated according to administrative procedures adopted by the MERCOSUR, taking into account technological progress and information on incidents involving the use or application of medical product.

### PART 3 - PROCEDURES FOR REGISTRATION

1. It is mandatory registration of all medical products framed in this document, except those products listed in Item 2, 3 and 12 below.



2. They are exempt from registration of medical products for clinical research, fulfilling the laws of the health authority responsible for carrying out these activities, being allowed to resell and / or use for other purposes.
3. They are exempt from registration of new presentations comprised of a set of medical products registered, and shall contain on the label and / or instructions for use the information for medical products.
4. The competent health authority shall grant the registration of medical products for families.
5. The manufacturers or importers to apply for registration of medical products framed in Classes II, III and IV must be submitted to the competent autoridades sanitarias the following documents:
  - a) Proof of payment of the fee.
  - b) Information to identify the manufacturer or importer and the medical device described in Annex III.A, III.B and III.C of this document, declared and signed by the legal and the technical manager.
  - c) Copy of authorization from the manufacturer or extra intra-zone or the exporter, the importer market your medical device in the receiving State Party of the product. When authorized by the exporter, the importer must demonstrate the commercial relationship between the exporter and manufacturer.
  - d) For imported medical products, proof of registration or certificate of free sale or an equivalent document issued by the competent authority in the country where the medical product is manufactured and / or marketed.
  - e) Proof of compliance with the laws determined by the technical regulations in the form of MERCOSUR legislation regulating this area.
6. The manufacturers and importers to apply for registration of medical products framed in class I, must submit to the competent health authority the documents specified in item 5 (a), 5 (b) and 5 (e).
7. The health authority will assess the documentation submitted for registration, alteration, or renewal of registration and manifest through an official document.
8. Once implemented this regulation, the health authorities of the States Parties have a period of 180 days for evaluation of the documentation and communication to interested.
9. Para request the amendment of the registration of medical product, the manufacturer or importer shall disclose at least the required documents in item 5 (a), and other documents required for the original record of the medical product, whose information was modified.



10. To apply for renewal of registration of medical product, the manufacturer or importer shall submit the information required in item 5 (a), as well as copies of original registration. This information should be submitted before the expiry of current registration, which will not disrupt the market.

11. The manufacturer or importer of the product registration holder physician may request the cancellation of registration by submission of Annex III A.

12. Record shall be exempt from attachment exclusively produced by a manufacturer to integrate their other medical product manufacturing has already been registered and whose technical report (Annex III C) the registration of this medical product containing information on this accessory. New accessories can be attached to the original record as such, detailing the basics of its operation, action and content.

13. The registration of medical products will be valid for 5 (five) years and may be revalidated in succession for the same period.

#### PART 4 - COMPLIANCE OF INFORMATION

1. Any alterations made by the manufacturer or importer in the information provided in these rules, referred to Item 5 of Part 3 of this document shall be communicated to the competent health authority within 30 (thirty) business days.

2. Any communication or advertising of the product released to the consumer market must keep strict accordance with the information provided by the manufacturer or importer to the competent health authority.

#### PART 5 - ADMINISTRATIVE SANCTIONS

1. As a health action and considering reasonable grounds, the health authority shall suspend the registration of medical products in the following cases:

a) is suspended, for duly justified safety reasons, the validity of any of the documents referred to in item 5 of Part 3 of this document.

b) is found non-compliance with any requirement of Part 4 of this document.

c) the product was under investigation by the competent health authority in terms of irregularities or defects in the product or manufacturing process, representing a risk to consumer health, patient, operator or third party involved, appropriately justified.

2. The health authority will cancel the registration of medical product if:

a) was proved the falsity of information shown on any of the documents referred to in item 5 of Part 3 of this regulation, or was canceled any of those documents by the competent health authority.



b) in case of verification by the competent medical authority that the product or manufacturing process may present a risk to consumer health, patient, operator, or others involved.

3. The suspension of registration of medical products will be published in an official document by the competent health authority will be maintained until the solution of the problem that caused the cancellation penalty and communicated through official document.

4. The cancellation of registration of medical products will be published in an official document by the competent health authority.

5. The health authority of a State Party of MERCOSUR, to cancel or suspend the registration of medical product be given within 5 working days, his decision to the authorities of other States Parties, technically justify the reasons for the cancellation or suspension. Similarly communicate the time and the reason for the lifting of the sanction, if any.

## DEFINITIONS

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

01 Accessory: Product made exclusively for the purpose of integrating a medical product giving the product an additional technical function or feature.

02 Consumer: any natural person using a medical product as the end user.

03 Manufacturer: any person who designs, manufactures, assembles or processes within the zone a finished medical product, including third parties authorized to sterilize, label, and / or wrapping.

Medical Product Family 04: A set of medical products, where each product has the technical characteristics described in item 1.1, 1.2 and 1.3 of the Technical Report (Annex III.C), similar.

05 Instructions for use: manuals, brochures or other documents that accompany the medical product containing technical information about the product.

06 Importer: legal person, public or private, the activity of a State Party to enter medical products manufactured outside.

07 reusable surgical instrument: an instrument for surgical use for cutting, drilling, sawing, milling, scraping, clamps, remove, clamping or some other similar procedure, with no connection to any active medical device, and can be reused a After making all appropriate procedures.

Lot or Item 08: The amount of a product made in a manufacturing or sterilization cycle, whose essential characteristic is the uniformity.

09 Operator: The person who carries out activities using a medical product.



10 hole of the body means any natural opening in the human body, including the eye socket or artificially created opening as a stoma.

11 Clinical Research: Research using human beings designed to verify the performance, safety and efficacy of a medical product, as MERCOSUR legislation available on this subject.

12 Period: Transient: Up to 60 minutes of continuous use.

Short Term: Up to 30 days of continuous use.

Long term: Greater than 30 days of continuous use.

13 Medical product: health product such as equipment, apparatus, material, item or system or application use medical, dental or laboratory, for the prevention, diagnosis, treatment, rehabilitation or that does not use contraception and pharmacological, immunological or metabolic to perform its primary function in humans, can meanwhile be assisted in its function by such means.

13.1. Active medical device: Any medical device operation of which depends on electrical power source or any other source other than power generated by the human body or gravity and which works for the conversion of this energy. Not be considered active medical products, medical products designed to provide, without causing any significant change, energy, substances or other elements between an active medical patient.

13.2. Product of active medical diagnostic means any active medical device, used singly or in combination with other medical products designed to provide information for the detection, diagnosis, monitoring or treatment of physiological or health conditions, diseases or congenital malformations.

13.3. Active medical device therapy: any active medical device, used singly or in combination with other medical products designed to support, modify, replace or restore biological functions or structures in the context of treatment or alleviation of disease, injury or handicap.

13.4. Single-use medical device means any medical device intended to be used in prevention, diagnosis, therapy or rehabilitation or contraception, usable only once, as specified by the manufacturer.

13.5. Implantable medical device means any medical device designed to be totally introduced into the human body, or to replace an epithelial surface or the ocular surface by surgical intervention and intended to remain there after the intervention. Also also considered an implantable any medical product intended to be partially introduced into the human body through surgical intervention and remain there after that long-term intervention.

13.6. Invasive medical device: medical device that penetrates wholly or partly within the human body, either through a body opening or through a body surface.



13.7. Medical device surgically invasive: invasive medical device that penetrates inside the human body through the body surface through or in the context of surgery.

14. LIABILITY: person powerful enough to represent a manufacturer or importer, whether in virtue of its corporate existence or power.

Technical 15.Responsible: university-level professional, trained in the technologies that make up the medical product, responsible for the technical information submitted by the manufacturer or importer and the quality, safety and efficacy of the marketed product.

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

17. Central Circulatory System: includes the following vessels: pulmonary arteries, ascending aorta, coronary arteries, 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 are governed by the intended use of medical products.

2. If a medical device intended to be used in combination with another medical device, the classification rules shall apply to each of the individual products.

Accessories are classified in their own right separately from the medical device being used.

3. The media (software), which drives a medical device or influences in their use will automatically be included in the same category.

4. If a medical product is not intended to be used solely or mainly on one specific body part will be considered for classification use more critical.

5. If for the same medical device several rules apply, taking into account the performance specified by the manufacturer shall apply the rules that lead to the higher classification.

6. For the purposes of applying the current classification of medical products to the resolutions adopted earlier in this document will proceed as follows:

a - above are Class I Class I of this document.

b - above are Class II Class II of this document.



c - Class III above are Class III and IV of this document.

## II. RULES

### 1. Noninvasive Medical Products

#### Rule 1

All non-invasive medical products are included in Class I, unless they qualify for one of the following rules.

#### Rule 2

All non-invasive medical devices for driving or storing blood, body fluids or tissues, liquids or gases for eventual infusion, administration or introduction into the body are in Class II:

a-if you can connect to an active medical device Class II or a higher class;

b-if they are to be used for storing or channeling blood or other body fluids or for storing organs, parts of organs or body tissues.

In all other cases they are in Class I.

#### Rule 3

All non-invasive medical devices intended for modifying the biological or chemical composition of the blood, other body fluids or other liquids intended for infusion into the body are in Class III, unless the treatment consists of filtration, centrifugation or exchanges gas or heat, in which case they are in Class II.

#### Rule 4

All non-invasive medical products that come in contact with injured skin:

to-be classified as Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,

b-are classified as Class III if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intention;

c-are included in Class II in all other cases, including medical products primarily intended to operate in the micro environment of a wound.

### Invasive Medical 2.Goods

#### Rule 5



All invasive medical products in relation to body orifices, other than surgically invasive medical products, which are not intended to be connected to an active medical device:

- a - are in Class I if they are intended for usotransitorio;
- b - are in Class II if they are destined for short term use, except when used in the oral cavity to pharynx, in the ear canal to the eardrum or nasal cavity, in which case they are in class I;
- c - are in Class III if used for prolonged use, except when used in the oral cavity to the pharynx, in the ear canal to the eardrum or nasal cavity, and can not be absorbed by the membranemucosa, in which case they are in Class II.

All invasive medical products in relation to body orifices, other than surgically invasive medical products, which are intended for connection to an active medical device Class II or a higher class in Class II.

#### Rule 6

All surgically invasive medical devices intended for transient use

in Class II unless:

- to - intended specifically to diagnose, monitor or correct a defect of the heart or central circulatory system through direct contact with these body parts, in which case they are in Class IV;
- b - reusable surgical instruments, in which case they are in Class I;
- c - intended to supply energy in the form of ionizing radiation, in which case they are in Class III;
- d - intended to exert a biological effect or to be absorbed fully or largely, in which case they are in Class III;
- e - is intended to administer medicines by means of an infusion system, if this is done in a potentially dangerous taking into account the mode of application, in which case they are in Class III.

#### Rule 7

All surgically invasive medical devices intended for short-term use are in Class II unless they are intended:

- a-specifically, diagnose, monitor or correct a defect of the heart or central circulatory system through direct contact with these body parts, in which case they are in Class IV, or
- b-specifically for use in direct contact with the central nervous system, in which case they are in Class IV, or



- c-supply energy in the form of ionizing radiation, in which case they are in Class III, or
- d-have a biological effect or be absorbed entirely or largely, in which case they are in Class IV, or
- e-undergo chemical change in the body unless the medical products are placed in teeth or to administer medicines, in which case they are in Class III.

#### Rule 8

All implantable medical devices and medical products long term invasive surgical type is included in Class III unless they are intended:

- a - to be placed in the teeth, in which case they are in Class II;
- b - to be used in direct contact with the heart, the central circulatory system or central nervous system, in which case they are in Class IV;
- c - to have a biological effect or be wholly or mainly absorbed, in which case included in Class IV;
- d - or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IV.

### 3. Additional rules applicable to active medical products.

#### Rule 9

All active therapeutic medical devices intended to administer or exchange energy are in Class II unless their characteristics are such that they can manage the human body energy exchange with the same potentially hazardous way, taking into account the nature, density and the point of application of energy, in which case they are in Class III.

All active medical devices intended to control or monitor the performance of active therapeutic medical devices in Class III or intended to directly influence the operation of these devices are in Class III.

#### Rule 10

All active medical products for diagnostic purposes are in Class II:

- a-if they are intended to supply energy which will be absorbed by the human body, except as medical products used to illuminate the body of the patient in the visible spectrum
- b-if they are intended to image in vivo distribution of radiopharmaceuticals;



c-if they intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, when the variations of those parameters, for instance variations in cardiac performance, respiration The central nervous system activity, may constitute an immediate danger to the patient's life, in which case they are in Class III.

The active medical products designed to emit ionizing radiation and intended for radiology for diagnosis and treatment, including devices which control or monitor those products or which directly influence the operation thereof, are included in Class III.

#### Rule 11

All active medical devices intended to administer medicines, body liquids or other substances to the organism, or extract thereof, are included in Class II, unless this is done in a potentially hazardous way, taking into account the nature of the substances , the body part in question and the mode of application, in which case they are in Class III.

#### Rule 12

All other medical assets are included in Class I.

### 4. Special Rules

#### Rule 13

All medical devices that incorporate as an integral part a substance which, if used separately, can be considered as a drug that may exert on the human body with action ancillary to that of medical products, are included in Class IV.

#### Rule 14

All medical products used for contraception or for prevention of transmission of sexually transmitted diseases are considered Class III products, unless they are implantable or invasive medical products long-term in which case they are in Class IV .

#### Rule 15

All medical products specifically for use of disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are included in Class III.

All medical products that are specifically intended for the disinfection of medical devices are in Class II.

This rule does not apply to products intended to clean medical devices other than contact lenses, through physical action.

#### Rule 16



Non-active medical products specifically intended for recording of radiographic images for diagnosis are in Class II.

Rule 17

All medical devices manufactured utilizing animal tissues or derivatives thereof which have been transformed into inert included in Class IV, except in cases where the products are intended to come into contact with intact skin only.

Rule 18

No derogation from other rules, blood bags are in Class III.

ANNEX III.A

INFORMATION FORM TO THE MANUFACTURER OR IMPORTER AND MEDICAL PRODUCTS

1. Type of Application:

- . Record
- . Revalidation
- . Disturbance
- . Cancellation

2. Identification of the Manufacturer or Importer registrant.

2.1. Identification Code for the functioning of the authorization granted to the establishment for the manufacture or importation of medical product.

2.2. Name of manufacturer or importer.

2.3. Fancy name of the manufacturer or importer, as appropriate.

2.4. Information from the manufacturer or importer.

Full address

Phone / Fax / E-mail.

3. Identification of medical product

3.1. Identification code and technical name of the medical device, (using universal naming or MERCOSUR when it becomes available).

3.2. Make and model (s) of (those) product (s) doctor (s) (describe or detail the family of medical products, as necessary).



3.3. Classification of medical product according to the rules laid down in Annex II of this document.

3.4. Medical Product Origin:

Manufacturer's name and complete address.

4. Legal responsibility and the technical manager of the establishment are responsible for the information provided on this form:

Name, title and signature of legal.

Name, title (career record) and signature of technician.

#### ANNEX III.B

#### SIGNS OF THE INFORMATION AND INSTRUCTIONS FOR USE OF MEDICAL PRODUCTS

##### 1. General Requirements

1.1 The information included on the label and use instructions should be written in the language of the State Party that is being applied for registration of medical product.

1.2 All medical products should include instructions for use in/with their packaging. As an exception, these instructions may be omitted from the packaging of Classes I and II medical products, as the safety of their use can be ensured without any such instructions.

1.3 The information needed to use the medical product with complete safety, must be included whenever feasible and appropriate on the medical device itself and /or unit package or, if possible, on the sales packaging.

If it is not feasible to package each individual unit, this information should be included in the instructions for use supplied with one or more medical products.

1.4 Where appropriate, the information shall be presented in the form of symbols and colors. Symbols and identification color used must conform to MERCOSUR regulations. If there are no regulations in this field, the symbols and colors are described in the documentation accompanying the product.

1.5 If a device-specific technical regulation requires additional information for the specific product, it will be incorporated into the label or instructions for use, if applicable.

##### 2. LABELS

The model of the label should contain the following information:

2.1. The name and address of manufacturer and importer, if applicable;



- 2.2. The details strictly necessary for the user to identify the medical product and content of the package;
- 2.3. If applicable, the word "sterile" [estéril]
- 2.4. The batch code, preceded by the word "lot" [lote] or the serial number as appropriate;
- 2.5. If applicable, date of manufacture and expiry date or the date before which it should be used to ensure complete safety;
- 2.6. If applicable to the device, the indication that the device is for single use only;
- 2.7. The conditions for storage, conservation, and /or handling;
- 2.8. Special instructions for operation and /or use of medical products;
- 2.9. Any warnings and /or precautions to take;
- 2.10. If applicable, the method of sterilization;
- 2.11. Name of legally qualified technician for the function;
- 2.12. Product Registration number preceded by the initials of the competent Health Authority.

### 3. INSTRUCTIONS FOR USE

The model of the instructions should contain the following information when applicable:

- 3.1. The information listed in item 2 of this regulation (Label), except those contained in item 2.4 and 2.5;
- 3.2. The benefits referred to in item 3 of the Annex to Resolution GMC No. 72/98 which deals with the essential requirements of Safety and Efficacy of Medical Products and unwanted side effects;<sup>1</sup>
- 3.3. When a medical device must be installed with other medical products or connect to them in order to work in accordance with its intended purpose, sufficient information should be provided about compatible devices to ensure a safe combination;
- 3.4. All information needed to verify that the medical product is properly installed and can operate correctly and with complete safety, as well as data concerning the nature and frequency of ongoing maintenance and calibration to ensure the smooth functioning and the safety of medical products;

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<sup>1</sup> [www.mercosur.int/msweb/Normas/normas\\_web/Resoluciones/ES/Res\\_072\\_098\\_RT\\_Req-Esenc\\_Seg-Eficacia\\_Prod-M%C3%A9dicos\\_Acta%204\\_98.PDF](http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/ES/Res_072_098_RT_Req-Esenc_Seg-Eficacia_Prod-M%C3%A9dicos_Acta%204_98.PDF)



3.5. The information to avoid certain risks related to the implementation of the medical product;

3.6. Information relative to the risks of mutual interference relating to the presence of the medical product in research or specific treatments;

3.7. The instructions in case of breakage of the protective sterile packaging and, if appropriate, an indication of the appropriate methods of re-sterilization;

3.8. If a medical device is reusable, information on proper procedures for reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the product must be re-sterilized, and any restriction on the number of reuses.

In case of medical products to be sterilized before use, instructions for cleaning and sterilization must be such that if followed correctly, the product continues to meet the requirements of Section I (General Requirements) of the Annex GMC Resolution No. 72/98 which deals with the essential requirements of safety and efficacy of medical products;

3.9. Information on any additional treatment or procedure to be performed before using the medical product (e.g., sterilization, final assembly, etc.);

3.10. For radiation emitting medical devices, information concerning the nature, type, intensity, and distribution of this radiation should be described;

The instructions for use must also include details allowing the medical staff to inform the patient about the contraindications and precautions to be taken. These details should cover in particular:

3.11. The precautions to be taken in case of changes in the performance of the medical product;

3.12. The precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration thermal ignition sources, including others;

3.13. Sufficient information on the drug or drugs that the medical product in question is designed to administer, including any restrictions on the choice of substances to be delivered;

3.14. The precautions to be taken if a medical device presents an unusual risk associated with specific disposal;

3.15. The drugs included in the medical product as an integral part thereof, pursuant to item 7.3.the Annex to Resolution No. 72/98 GMC available on the Essential Requirements of Safety and Efficacy of medical products;



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

ANNEX III.C

TECHNICAL REPORT

1. The technical report must have the following information:

1.1 Description of the medical product details, including the basics of its operation and its action, its content or composition, as appropriate, and details of accessories to integrate the medical product;

1.2 Indication, purpose or intended use to which the medical product as indicated by the manufacturer;

1.3 Caution, restrictions, warnings, special care and clarification on the use of medical products, such as storage and transportation;

1.4 Vessel form of presentation of the medical product;

Flowchart 1.5 containing stages of medical product manufacturing, with a brief description of each stage of the process to obtain the finished product

1.6 Description of the efficacy and safety of medical product in accordance with Resolution

GMC No. 72/98 governing on the essential requirements of Safety and Efficacy of Medical Products. In the event that this description does not verify the efficacy and safety of medical product, the Health Authority shall request the product of clinical research.

2. In the case of applying the Registration of Class I Medical framed in the technical report of such petition shall contain only the information specified in item 1.1 to 1.4 of this Annex III.C.

3. Legal responsibility and the technical manager of the establishment shall assume responsibility for the information presented in the technical report which shall be signed by the same clarifying name, title and professional registration.

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