RESOLUTION RDC NO. 40, OF AUGUST 26, 2015

Defines all medical product *cadastro* registration requirements

The Joint Board of Directors of the Brazilian Health Surveillance Agency (ANVISA), in exercise of the powers conferred by items III and IV of Art. 15 of Law No. 9.782 of January 26, 1999, of item V and paragraphs 1 and 3 of Art. 58 of its Internal Regulations approved as per the terms of Annex I of Joint Board of Directors Resolution - RDC No. 29 of July 21, 2015 published in the Federal Official Gazette of July 23, 2015, considering the provisions of item III of Art. 2, items III and IV of Art. 7 of Law No. 9.782 of 1999, and the Agency's Regulation Process Improvement Program, instituted by Ordinance No. 422 of April 16, 2008, and as agreed to at a meeting held on August 20th, 2015, hereby adopts the following Joint Board of Directors resolution, and I, as current Chairman, order its publication.

CHAPTER I
INITIAL PROVISIONS

Section I
Purpose

Art. 1 The following resolution aims at defining the *cadastro* registration requirements for the sanitary control of medical products exempt from *registro* registration, as per paragraph 1, of Art. 25, of Law No. 6.360, of September 23, 1976.

Section II
Scope

Art. 2 This Resolution applies to all medical products classified as Class I and II by Joint Board of Directors Resolution – RDC No. 185 of October 22, 2001.

Sole paragraph. This resolution does not apply to in-vitro diagnostic products, which shall be regulated by a specific resolution.

Section III
Definitions

Art. 3 Under this Resolution, the following definitions apply:

I- *Cadastro* product registration: act exclusive to ANVISA, after evaluation and concession statement issued by its director, to confirm the right of manufacture and importation of the medical product exempted of *registro* registration as per the terms of paragraph 1, of Art. 25 of Law No. 6.360 of 1976, indicating the name, manufacturer, purpose and other pertinent characteristics; and

II- technical dossier: document that describes all elements that comprise the product, indicating their characteristics, purpose, mode of operation, content, special health restrictions, potential risks, manufacturing process and other additional information.

CHAPTER II
INITIAL CADASTRO REGISTRATION REQUEST

Art 4 In order to request medical product *cadastro* registration, the manufacturer or importer must submit the following:

I- *cadastro* application form, available at the ANVISA website, duly completed, in both printed and electronic (CD or DVD) formats;

II- proof of payment of the Sanitary Surveillance Supervision Inspection Fee (TFVS), attested by the presentation of a Federal Tax Payment Form (GRU), or an exemption form, corresponding to the request submitted;

III- Authenticated copy of the Compliance Certificate issued by the Brazilian Compliance Assessment System (SBAC), applicable only to devices subject to compulsory certification, as listed by ANVISA in specific regulation;

IV- for imported medical products, a consular declaration along with its sworn translation, issued no less than two years prior by the responsible manufacturer(s) when no validity date is included in the document, duly authorizing the importer to represent and commercialize the product(s) in Brazil. This declaration must contain the following information:

a) manufacturer's legal name and complete address;

b) importer's legal name and complete address;

c) express authorization issued by the manufacturer authorizing the importer to represent and commercialize its products in Brazil;

d) knowledge and compliance with Good Manufacturing Practices requirements for health products, established by Joint Board of Directors Resolution – RDC No. 16, of March 28, 2013.

§1. For technical reasons, in order to prove the safety and effectiveness of the products due to potential public health risks, and for those products considered strategic by the Ministry of Health, ANVISA may request the submission of additional documentation and information.

§2. Requests submitted with missing documents, incomplete forms or declarations, or with missing information will not be eligible for technical requirements, and will be summarily rejected.

Art. 5 The concept of family, system and set grouping of products are applicable in the *cadastro* registration process.

Sole paragraph. The grouping of products intended for *cadastro* registration will be considered according to rules established by ANVISA Resolutions.

CHAPTER III
CADASTRO REGISTRATION AMENDMENTS

Art. 6 For requests for amendments to the *cadastro* of health products either the manufacturer or the importer must provide:

I- *cadastro* application form, available at the ANVISA website, duly updated, highlighting the amendment requested, in both printed and magnetic (CD or DVD) formats;

II- proof of payment of the Sanitary Surveillance Supervision Inspection Fee (TFVS), by means of presentation of tax payment form (GRU), or exemption form according to the type of request submitted;

III- the declaration appearing in ANNEX I of this Resolution, signed by the legal and technical representatives; and

IV- other documents indicated in Art. 4, which, due to the requested amendment, must also be updated.

Sole Paragraph. Requests containing missing documents, uncompleted forms or declarations, or with missing information will not be eligible for technical requirement, and will be summarily rejected.

Art. 7 In those cases in which the amendment requires the depletion of stock of finished products, the simultaneous import and sale of versions involved will be allowed for a period of 180 (one hundred and eighty) days, as of the date ANVISA approved the amendment.

Sole Paragraph. Amendment requests made to address problems regarding the safety and effectiveness of a product are not eligible for approval according to the aforementioned article, and must be implemented before the product is sold or distributed.

CHAPTER IV
CADASTRO REGISTRATION CONTROL

Art. 8 It is the responsibility of the national manufacturer or importer to maintain an updated technical dossier, with all documents and information indicated in ANNEX II of this Resolution, for surveillance purposes by the National Sanitary Surveillance System.

Art. 9 Equipment *cadastros* that are subject to sanitary surveillance and that have been registered must have an indelible label affixed, indicating the following:

I- the product trade name, and model number, when applicable;

II- name of the legal manufacturer;

III- *cadastro* registration number; and

IV- serial number or any other identifier that enables both the traceability and unique identification of the equipment.

§1 For equipment of reduced size, on which it is not possible to affix such labels, it is obligatory that a mark indicating the brand as well as traceability elements be fixed on the device.

§2 In the case of systems, all components must be identified as being part of the system they comprise.

CHAPTER V
CADASTRO REGISTRATION VALIDITY PERIOD

Art. 10 Products subject to *cadastro* registration are exempt from renewal.

§1 The maintenance of a *cadastro* depends on full compliance with Good Manufacturing Practices, with applicable technical standards, and with specific regulations, when they exist.

§2 Products which are subject to compliance certification by the Brazilian Compliance Assessment System (SBAC) may only be imported and commercialized with a valid Compliance Certificate, according to the product's date of manufacturing.

CHAPTER VI
CADASTRO REGISTRATION CANCELLATION

Art. 11 ANVISA will cancel a medical product *cadastro* registration in the following situations:

I- when any of the information provided is proven to be false or when any of documents indicated in Art. 4 is cancelled, or

II- when it is proven that either the product or manufacturing process presents a risk to the health of consumers, patients, technicians or involved third parties.

Art. 12 The holder of the medical product *cadastro* registration that no longer intends to commercialize the product on the Brazilian market must request cancellation of the *cadastro* by submitting a specific form, which is available on ANVISA’s website, duly completed and signed by both the legal and technical representatives.

Sole Paragraph. Cancellation of the *cadastro* does not exempt the registration holder from responsibilities regarding products placed on the market.

CHAPTER VII
TRANSITIONAL AND FINAL PROVISIONS

Art. 13 Products registered as Class I and II *registro* shall become considered *cadastro*, keeping the same registration ID number, and do not require renewal.

Art. 14 Products registered as Class I and II *registro* and those already registered as *cadastro* must comply with the terms of Art. 8, within the timeframe defined in Art. 19, with no need of submitting the updated version of the form for applications already at ANVISA, except in cases of amendment requests, which must comply with the terms of Chapter III.

Art. 15 The *cadastro* review process will be applied to applications for Class I and II medical products for which technical analysis is still pending, it being up to the company to request such amendment to ANVISA, through a duly completed *cadastro* application form, available at ANVISA's website, to be submitted in both printed and electronic formats (CD or DVD).

Art. 16 The same sanitary violations and associated penalties applicable to the medical product *registro* system are also applicable to the *cadastro* system.

Art. 17 All documents mentioned in this Resolution that are issued in English must be translated to Brazilian Portuguese.

Sole Paragraph. Technical reports included in the Technical Dossier indicated in Art. 8 are exempt from the translation requirement, pursuant to Joint Board of Directors Resolution – RDC No. 50, of November 6, 2013.

Art. 18 The terms of Art. 8 must be complied with within 365 (three hundred and sixty five) days from the date of publication of this Resolution, and apply to both new and old *cadastros*.

Art. 19 As of the day this Resolution becomes effective, the following are revoked: Joint Board of Directors Resolution – RDC No. 24, of May 21, 2009, ANVISA Norm – IN No. 13, of October 22nd, 2009 and the Art. 3 of Joint Board of Directors Resolution – RDC No. 185, of October 22, 2001.

Art. 20 This Resolution shall become effective 60 (sixty) days after the date of its publication.

JARBAS BARBOSA DA SILVA

ANNEX I

CADASTRO AMENDMENT DECLARATION

We hereby declare that the amendments described in the documents, both printed and electronic, submitted in this application correspond exclusively to the following subject _____. Reflected in the following amendments:

1. _____
2. _____
3. _____
4. _____
5. _____
(…) _____

We are aware that any other amendments, which are not covered under the indicated subject, shall be disregarded, and may lead to the denial of the request.

Company's Legal Name – CNPJ
Location and date
Signature of the company's legal and technical representatives

ANNEX II

MEDICAL PRODUCT TECHNICAL DOSSIER

1. It is not required that the Technical Dossier be in a physical or electronic format with all information described below, and may be comprised of references to documents and information in other files or records in the company's Quality System records, which should be available for review by the National Sanitary Surveillance System.

2. This Technical Dossier should not be submitted to ANVISA as part of a product's *cadastro* request, and must remain in the possession of the registration holder company.

2.1 Technical Dossiers may be subject to audit, as per the terms of Art. 8 of this Resolution.

2.2 In specific cases, when enquiries and investigations are required, ANVISA may request the submission of the Technical Dossier.

3. Medical product Technical Dossiers must contain all the information listed in the table below, as applicable, considering the nature of the product technology and its risk class.

3.1 Details regarding the information listed below will be provided in specific guides, published or referenced by ANVISA.

3.2 All reports included in the Technical Dossier are summarized; however, complete reports may be required in cases in which more detailed information is necessary.

Chapter 1	**Class I**	**Class II**
Submission Form: Administrative/Technical Information	X	X
List of Devices (models, components, variations). Note: in case of family, system or set.	X	**X**
Manufacturer Letter of Authorization Note: only for imported products.	**X**	**X**
Chapter 2	**Class I**	**Class II**
Complete description and operational principles of the device.	X	X
Packaging description of the device	X	X
Intended use; Purpose; Intended user, Indication of use.	X	X
Intended use environment/setting	X	X
Device contraindications	X	X
Global history of commercialization	---	X
Chapter 3	**Class I**	**Class II**
Risk Management	X	X
List of Essential Safety and Effectiveness Requirements	---	X
List of Technical Standards	X	X
SBAC Compliance Certificate Note: for products subject to compulsory certification only	X	X
Physical/Mechanical Properties	X	X
Material/Chemical Properties	X	X
Electrical Systems: Safety, environmental and mechanical protection, and electromagnetic compatibility	X	X
Software/Firmware Description	X	X
Software Requirement Specifications	---	X
Brief description of software lifecycle process	---	X
Software verification and validation	X	X

Biocompatibility Assessment	X	X
Pyrogenicity Assessment	X	X
Safety of Biological Material	X	X
Sterilization validation	X	X
Residual toxicity	X	X
Cleaning and Disinfection of Reusable Products	X	X
Usability/Human Factors	X	X
Product expiration date and packaging validation/ Stability Study	X	X
Chapter 4	**Class I**	**Class II**
General Summary of Clinical Evidence Note: applicable only when clinical evidence is required in order to demonstrate safety and efficacy, for innovative technologies and new indications of use.	X	X
Relevant Clinical Literature	---	X
Chapter 5	**Class I**	**Class II**
Product labeling and packaging	X	X
Product information/instructions for use/operating manual	X	X
Chapter 6	**Class I**	**Class II**
General information about the product (production location and production flowchart)	X	X
Design and Development Information	X	X