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COLLEGIATE BOARD RESOLUTION - RDC No. 556, OF AUGUST 30, 2021

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It provides for the requirements for grouping materials for use in health for registration and notification purposes in the National Health Surveillance Agency and adopts traceability labels for implantable products.

The Collegiate Board of the National Health Surveillance Agency, in the use of the competences that confer on it the arts. 7, item III, and 15, items III and IV, of Law No. 9,782, of January 26, 1999, and considering the provisions of article 53, item VI and §§ 1 and 3, of the Internal Regulations, approved by the Collegiate Board Resolution – RDC No. 255, of December 10, 2018, resolves to adopt the following Resolution of the Board of Directors, as resolved at a meeting held on August 30, 2021, and I, the Chief Executive Officer, determine its publication.

CHAPTER I
INITIAL PROVISIONS

Section I
Purpose and Scope

Art. 1° This Resolution establishes the requirements and definitions for the grouping of materials for use in health for the purposes of registration and notification in ANVISA and adopts traceability labels for implantable products.

Art. 2° This Resolution applies to materials for use in health.

§ 1 - Implantable products applied in orthopedics are excluded from this Resolution.

§ 2 - Except for the general criteria for grouping set forth in this Resolution are the materials for use in health contemplated in Normative Instruction of specific criteria for grouping or in other specific technical regulations.

Section II
Definitions

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

I. – accessory: product manufactured exclusively for the purpose of integrating a medical product granting it a complementary function or technical characteristic;

II. - commercial presentation: all the ways in which the product is presented for consumption, including a description of the form of packaging and the contents of the packaging;

III. - set (kit, set or tray): grouping of materials for use in health from the same manufacturer

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or manufacturing group, used in a specific procedure and that, in isolation, do not maintain a relationship of interdependence to obtain the functionality and performance for which it is intended;

IV. - Traceability Label: complementary document to be provided with the material for use in health, containing field for insertion of the following information:

a) name or business model;

b) identification of the manufacturer or importer;

c) product or system component code; and

d) batch number and registration number with ANVISA;

I. - product family: grouping of materials for use in health that may belong to the same registry or notification and that follow general criteria established and, when applicable, specific criteria or defined in specific technical regulation;

II. - indication of use: determination of the use for which the material for use in health is intended;

III. - raw material: substances that are used in the manufacture of materials for use in health, both those that remain unchanged and those that can undergo modifications;

IV. - implantable health use materials: any health use material designed to be fully or partially introduced into the human body or to replace an epithelial or ocular surface, by means of surgical intervention, and intended to remain in place after the intervention and remain after this intervention for more than thirty (30) days;

V. - permanent use implantable health materials: any health use material designed to be fully or partially introduced into the human body or to replace an epithelial or ocular surface, by means of surgical intervention and intended to remain in place after the intervention and remain after this intervention for an indefinite period;

VI. - mechanism of action: principle of functioning of a material for use in health, so that it acts or interacts with the organism in order to obtain the purpose for which it is proposed;

VII. - commercial model: material for use in health that is part of a family;

VIII. - part: a component manufactured exclusively for the purpose of integrating a health product, without which the product is functionally deficient or inoperable; and

IX. - System: product of the same manufacturer or manufacturing group, consisting of complementary and compatible components and exclusive use among themselves, for a single and specific function, which maintain a relationship of interdependence to obtain functionality, intended for a certain procedure and whose performance is only obtained if used in an integrated way.

CHAPTER II

REQUIREMENTS FOR THE GROUPING OF MATERIALS FOR USE IN HEALTH FOR REGISTRATION AND NOTIFICATION PURPOSES AND ADOPTION OF TRACEABILITY LABELS FOR IMPLANTABLE PRODUCTS

Art. 4° The systems and sets of materials for use in health are equivalent to families for the purpose of collecting health surveillance fees.

Art. 5° The codes or names associated with the commercial models, parts, components and

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accessories of the materials for use in health presented in the documentation of the notification processes or petitions, when applicable, must be declared in the Manufacturer's or Importer's Form and in the Technical Report presented in the documentation of the registration processes, parts, components and accessories of the materials for use in health, as well as variations in size.

Art. 6 The comparative table of commercial models, parts, components and accessories of materials for use in health must be presented as a document attached to the registration and notification process or petitions.

Art. 7° The materials for use in health with different concentrations, obeying all the general criteria, can be grouped in the family.

Art. 8° The grouping in family of materials for use in health must meet the following general criteria:

I - Health use materials subject to notification and registration must belong to a same manufacturer or manufacturing group and have the same operating principle, mechanism of action, indication of use, contraindication, adverse effect, precaution, restriction, warning, special care, storage, condition and risk class.

II - materials for use in health care subject to notification and registration must have similar raw material and manufacturing technology;

III - sterile and non-sterile products subject to notification and registration cannot be grouped into the same family;

IV - products subject to notification and registration whose manufacturer recommends single use and products subject to reprocessing cannot be grouped into the same family; and

V - Products subject to notification and registration of prohibited reprocessing and products subject to reprocessing may not be grouped into the same family.

Single paragraph. Notification and registration in the set or system family is not allowed.

Art. 9 The variations of color, aroma and flavor are considered as a form of commercial presentation, not characterizing family of materials.

Art. 10. Dimensional variations are considered family business models of materials.

Art. 11. Variation of the commercial presentation is not allowed with the exclusion of components. or materials in the process of system or set notification or registration.

§ 1 - For replacement purposes, the components of the system may be marketed separately provided that they are for the exclusive use of the system.

§ 2 - Must appear on the label and instructions for use of the replacement component of the system:

- the trade name of the system and the name of the replacement component, as informed in the registration process; and

- the words "replacement component for exclusive use in the system".

Art. 12. For replacement purposes, the materials of the instrument set, intended exclusively for a specific procedure, may be marketed separately, provided that they are for the exclusive use of that procedure.

Single paragraph. They shall appear on the label and instructions for use of the replacement component of the instrument assembly:

I - the trade name of the assembly and the name of the replacement component as entered in

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the notification or registration process; and

II - the words "replacement component for exclusive use in the instrumental set".

Art. 13. The components of the system and the materials of the assembly may have different risk classes, always applying the highest risk class.

Art. 14. The dimensional variation of the components of the system and the materials of the assemblies is considered as a form of commercial presentation, not characterizing family of systems or family of sets.

Art. 15. For the purposes of registry or notification changes, it is possible to add, exclude, or replace components in the system and assembly, provided that this does not mischaracterize the original product.

Art. 16. The quantitative variation of the components of a set characterizes a form of commercial presentation, provided that no component of this set is excluded

Art. 17. For implantable health materials of permanent use of high and maximum risk, the manufacturer or importer must provide traceability labels with the identification of each implantable system material or component.

§1 At least three (3) labels must be made available for mandatory fixation: in the clinical record, in the document to be delivered to the patient, and in the fiscal documentation that generates the charge.

§2 The provisions of this article shall not apply to suture threads.

CHAPTER III

FINAL PROVISIONS

Art. 18. Failure to comply with the provisions contained in this resolution and in the regulation approved by it constitutes a health infraction, under the terms of Law No. 6,437, of August 20, 1977, without prejudice to the applicable civil, administrative and criminal liability.

Art. 19. The Collegiate Board Resolution – RDC No. 14, of April 5, 2011, published in the Official Gazette No. 69, of April 11, 2011, is hereby revoked.

Art. 20. This Resolution takes effect on October 1, 2021.

ANTONIO BARRA TORRES

Chief Executive Officer