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RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS - RDC No. 546, OF AUGUST 30, 2021

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It provides the essential safety and efficacy requirements for health products.

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the attributions conferred on it by article 15, III and IV, together with article 7, III and IV of Law No. 9,782, of January 26, 1999, and article 53, VI, §§ 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, as resolved at a meeting held on August 30, 2021, and I, the Chief Executive Officer, determine its publication.

CHAPTER I
INITIAL PROVISIONS

Art. 1 This Resolution provides for the essential safety and efficacy requirements applicable to health products and internalizes the Mercosur/GMC/Res. Resolution No. 72/98.

Art. 2 Health products must meet the essential requirements of safety and efficacy set forth in this Resolution.

Single paragraph. The health products referred to in this Resolution are the products defined as "correlated" by Law No. 6,360, of September 23, 1976, with the exception of products for in vitro diagnosis.

Art. 3 The requirements of this Resolution must be met by manufacturers and importers in their products.

Art. 4 The verification of the conformity of health products to the essential requirements is carried out by the sanitary surveillance authority on the occasion of the inspection of Good Manufacturing Practices, the registration of products with ANVISA or the sanitary inspection of the products.

Art. 5 Compliance with articles 6 and 9 of this Resolution shall be based on clinical data, particularly in the case of health products of classes III or IV, according to the risk classification of these products present in Collegiate Board Resolution No. 185 of October 22, 2001 or another that may replace it.

Single paragraph. The adequacy of the clinical data shall be based on the following information:

- compilation of the scientific bibliography of indexed publications related to clinical research, on the proposed use of the product for health, and when appropriate, written report containing a critical evaluation of this bibliography; or

- results and conclusions of a clinical research specifically developed for the health product.

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CHAPTER II
GENERAL PROVISIONS

Art. 6 Health products must be designed and manufactured in such a way that their use does not compromise the clinical status and safety of patients, nor the safety and health of operators or, where appropriate, other people, when used under the conditions and purposes envisaged.

Single paragraph. Possible existing risks should be acceptable in relation to the benefit provided to the patient and should be reduced to a degree compatible with the protection of the health and safety of persons.

Art. 7. The solutions adopted by the manufacturer for the design and manufacture of health products must conform to the updated principles of the technology.

Art. 8 When selecting the most appropriate solutions, the manufacturer shall apply the following principles, in the following order:

- eliminate or reduce risks as far as possible (safety inherent in design and manufacturing);

- adopt appropriate protective measures, including alarms, when necessary, against risks that cannot be eliminated; and

- inform operators of residual risks due to the incomplete effectiveness of the protective measures adopted.

Art. 9 Health products must have the performance assigned by the manufacturer and perform their functions as specified by the manufacturer.

Art. 10. The characteristics and performance of health products shall not change to such a degree as to jeopardize the clinical status and safety of patients or consumers or, where appropriate, of other persons, for the duration of the period of validity provided for by the manufacturer and under normal conditions of use.

Art. 11. Health products must be designed, manufactured and packaged in such a way that their characteristics and performance, according to their intended use, are not altered during storage and transport, taking into account the instructions and data provided by the manufacturer.

Art. 12. Any undesirable side effect should constitute an acceptable risk in relation to the assigned performance.

CHAPTER III
DESIGN AND MANUFACTURE

Section I
Chemical, physical and Biological Properties

Art. 13. Health products must be designed and manufactured in such a way that the characteristics and performance mentioned in article 6 are guaranteed, with special attention to:

- selection of the materials used, particularly in terms of toxicity and, where appropriate, flammability; and

- compatibility between the materials used and between the materials and biological

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tissues, cells and body fluids, taking into account the intended purpose of the medical product.

Art. 14. Health products must be designed, manufactured and packaged in such a way that the risk presented by contaminants and residues to people participating in transport, storage and use, as well as to patients, is minimized, considering the intended purpose of the product.

Single paragraph. Special attention should be paid to exposed tissues and the duration and frequency of exposure.

Art. 15. Health products must be designed and manufactured so that they can be used completely safely with materials, substances and gases with which they come into contact during their normal use and in usual procedures.

Single paragraph. In the event that health products are intended for the administration of medicinal products, such products shall be designed and manufactured in a manner compatible with the medicinal products covered by the provisions and restrictions governing such products and their use shall be permanently adjusted to the purpose for which they are intended.

Art. 16. Health products must be designed and manufactured in such a way that the risks arising from the substances detached from them are minimized.

Section II

Infection and Microbial Contamination

Art. 17. Health products and their manufacturing processes must be designed in such a way as to eliminate or reduce the risk of infection for the patient or consumer, operator or third parties involved.

Art. 18. Tissues of animal origin must come from animals which have undergone appropriate veterinary controls and monitoring, depending on the intended use of these tissues.

Art. 19. Tissues, cells and substances of animal origin shall be processed, preserved, analysed and manipulated in such a way as to offer maximum guarantees of safety.

Art. 20. Recognised methods of viral elimination or inactivation shall be used during the manufacturing process which offer guarantees against viruses and other transmissible agents

Art. 21. Health products supplied in a sterile state must be designed, manufactured and packaged in non-reusable packaging or according to appropriate procedures, in such a way that they are sterile at the time of their marketing and that they maintain this quality under the conditions of storage and transport, until the protective packaging that guarantees sterility is violated or opened.

Art. 22. Health products supplied in a sterile state must be manufactured and sterilized by appropriate and validated methods.

Art. 23. Health products that must be sterilized must be manufactured under adequately controlled conditions, such as those relating to the environment.

Art. 24. Packaging systems intended for non-sterile health products should keep the product without deterioration in the intended state of cleanliness and, if the product needs to be sterilized before use, the risk of microbial contamination should be minimized.

Single paragraph. The packaging system must be appropriate according to the sterilisation method indicated by the manufacturer.

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Art. 25. The packaging or labelling of health products must enable products which are identical or similar in their forms of presentation, sterile and non-sterile, to be clearly distinguished and at plain sight.

Section III

Properties Relating to Manufacturing and the Environment

Art. 26. When a health product is intended for use in combination with other products or equipment, the combination, including the connection system, must be safe and not alter the intended performance.

Single paragraph. Any restrictions on use should be indicated on the labels or in the instructions for use.

Art. 27. Health products must be designed and manufactured in a way that eliminates or reduces:

- the risks of injuries linked to their physical characteristics, including the volume/pressure ratio, the dimension, and, if applicable, ergonomics;

- risks linked to reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharges, pressure, temperature or variations in pressure and acceleration;

- the risks of reciprocal interference with other products, normally used for diagnosis or therapy; and

- the risks derived, in case of impossibility of maintenance or calibration, from the ageing of the materials used or from the loss of precision of any mechanism or control.

Art. 28. Health products must be designed and manufactured in such a way that under normal conditions of use the risks of fire or explosion are minimized.

Single paragraph. Particular attention should be paid to products which are exposed to substances or gases which are flammable or capable of promoting combustion.

Section IV

Products with Measuring Function

Art. 29. Health products with a measuring function must be designed and manufactured in such a way that they provide sufficient stability and accuracy of measurement within the limits appropriate to the purpose of the product.

Single paragraph. The precision limits shall be indicated by the manufacturer.

Art. 30. The scale of measurement, control and visualization should be designed making it easier to read, taking into account the purpose of the product.

Section V

Radiation Protection

Art. 31. Health products must be designed and manufactured in such a way that any

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exposure of patients, operators and other persons to radiation is kept to a minimum, compatible with the intended purpose, without limiting the application of the appropriate levels indicated for therapeutic or diagnostic purposes.

Subsection I
Intentional Radiation

Art. 32. Where health products are designed to emit dangerous levels of radiation necessary for a specific medical, therapeutic and/or diagnostic purpose, the benefit of which is considered to outweigh the risks inherent in the emissions, these will have to be controlled by the operator.

Single paragraph. The products specified in the caput of this Article shall be designed and manufactured in such a way as to ensure the repeatability and tolerance of the relevant variable parameters.

Art. 33. Where health products are intended to emit potentially dangerous radiation, visible and/or invisible, they shall be equipped with visual and/or audible indicators signalling the emission of radiation.

Subsection II
Unintentional Radiation

Art. 34. Health products should be designed and manufactured in such a way as to minimise the exposure of patients, operators and others to the emission of unintended, parasitic or dispersed radiation.

Subsection III
Instructions for Use

Art. 35. The instructions for use of health products emitting radiation shall include detailed information on the characteristics of the radiation emitted, the means of protecting the patient and the operator and ways to avoid mishandling and to eliminate the risks arising from the installation.

Subsection IV
Ionizing Radiation

Art. 36. Health products that emit ionizing radiation must be designed and manufactured in such a way that the quantity and quality of the radiation emitted can be regulated and controlled, according to the objective pursued.

Art. 37. Health products that emit ionizing radiation for radiological diagnosis must be designed and manufactured to ensure good image and/or result quality according to the medical purpose sought, with minimal patient and operator exposure to radiation.

Art. 38. Health products emitting ionizing radiation intended for radiotherapy must be designed and manufactured in a way that allows for reliable surveillance and control of administered doses, type of beam, energy, and type of radiation.

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Subsection V

Requirements for Medical Products Connected or Equipped with a Power Source

Art. 39. Health products that incorporate programmable electronic systems must be designed in a way that ensures the repeatability, reliability and effectiveness of these systems, in line with their intended use.

Single paragraph. In the case of conditions of first defect in the system, provision should be made for the means to be able to eliminate or reduce, as far as possible, the consequential risks.

Art. 40. Health products which have an internal energy source on which the safety of patients depends must be provided with means to determine the state of the energy source.

Art. 41. Health products connected to an external power source on which patient safety depends must include an alarm system that indicates any failure of the power source.

Art. 42. Health products intended to monitor one or more clinical parameters of a patient must have appropriate alarm systems to alert the operator of situations that may cause risk conditions or aggravate the patient's state of health.

Art. 43. Health products should be designed and manufactured in such a way as to minimize the risks of generating electromagnetic fields that could impair the operation of other products in your vicinity.

Subsection VI

Protection against electrical hazards

Art. 44. Health products must be designed and manufactured in such a way that, when properly installed and used under normal conditions or in a first defect condition, the risks of accidental electric shock are eliminated.

Subsection VII

Protection against mechanical and thermal hazards

Art. 45. Health products must be designed and manufactured so that patients or operators are protected from mechanical hazards from, for example, strength, stability or moving parts.

Art. 46. Health products shall be designed and manufactured in such a way that the risks arising from vibrations produced by the products are reduced to the minimum possible level, taking into account technological progress and the availability of means for reducing vibrations, especially at their source, unless the vibrations form part of the specifications laid down for the product.

Art. 47. Health products must be designed and manufactured in such a way that the risks arising from noise emission are reduced to the minimum possible, taking into account technological progress and the availability of means to reduce noise, especially at its source, unless noise is part of the expected performance.

Art. 48. Terminals and connectors of health products for electrical, hydraulic, pneumatic or gaseous energy that have to be handled by the operator, must be designed and manufactured in such a way as to minimize any possible risk.

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Art. 49. Accessible parts of health products (excluding parts or areas intended to provide heat or to reach certain temperatures) and their surroundings may not reach temperatures which pose a danger under normal conditions of use.

Subsection VIII

Protection against risks that may present to the patient the sources of energy or administration of substances

Art. 50. The design and manufacture of health products intended to provide energy or substances to the patient must be granted so that the flow can be regulated and maintained with sufficient precision to ensure patient and operator safety.

Art. 51. The health product must be provided with means to prevent and/or indicate any inaccuracy in the flow of energy or substance, when any danger may arise from it.

Art. 52. Health products must be equipped with adequate means to prevent the accidental release of dangerous levels of energy and/or substances.

Art. 53. The function of controls and indicators should be clearly indicated in health products.

Single paragraph. In the event that a health product is accompanied by instructions necessary for its use or indications for control or regulation by means of a visual system, such information must be comprehensible to the operator, and if applicable, to the patient or consumer.

CHAPTER IV
FINAL PROVISIONS

Art. 54. Failure to comply with the provisions contained in this Resolution 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. 55. The Resolution of the Collegiate Board of Directors - RDC No. 56, of April 6, 2001, published in the Official Gazette No. 70, of April 10, 2001, Section 1, p. 28, is repealed.

Art. 56. This Resolution takes effect on October 1, 2021.

ANTONIO BARRA TORRES