RDC no. 56, April 6th, 2001

The Collegiate Board of Directors of the Brazilian National Health Surveillance Agency, 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 April 4th, 2001,

considering the need to establish minimal requirements for safety and efficacy of healthcare products;

considering that clinical data, obtained from clinical researches conducted with healthcare products, are essential indicators of safety and efficacy of these products;

considering that the compliance with the requirements for safety and efficacy of healthcare products must be verified by the competent health surveillance authority since the inspection of production, upon registration, until the inspection in the market;

considering the need to internalize GMC Mercosur Resolution no. 72/1998, which approved the technical regulation containing the essential requirements for safety and efficacy of medical devices,

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

Article 1. Healthcare products shall comply with the applicable essential requirements for safety and efficacy referred to in the annex hereof.

Sole Paragraph. The healthcare products herein addressed are the products defined as medical devices by Law 6,360/1976 and Decree 79,094/1977, not enclosing in-vitro diagnostic products.

Article 2. Compliance of healthcare products with the essential requirements shall be verified by the health surveillance authority upon inspection of Good Manufacturing Practices, upon product registration at Anvisa, or sanitary inspection.

Article 3. Failure to comply with the provisions hereof implies the imposition of penalties established in sanitary legislation.

Article 4. This Resolution shall come into force on the date of its publication.

GONZALO VECINA NETO

ANNEX

TECHNICAL REGULATION

ESSENTIAL REQUIREMENTS FOR SAFETY AND EFFICACY OF HEALTHCARE PRODUCTS

Principles

1. This regulation approves the minimal requirements with which manufacturers and importers must comply, seeking to unify the criteria for the information requested by the health surveillance authority pertaining to the safety and efficacy of healthcare products.
2. The compliance with the requirements established in items 1 and 3 of the General Requirements of this regulation must be evidenced by clinical data, especially in the case of healthcare products of class III or IV, according to their risk classification.

3. Considering the applicable technical regulations, the adequacy of clinical data must be based on the following information:

   a) compilation of scientific bibliography of indexed publications related to clinical researches on the product’s intended use and, if applicable, related to written reports containing a critical review of this bibliography; or

   b) results and conclusions of a clinical research specifically conducted on the product.

I. General Requirements

1. Healthcare products must be designed and manufactured in a way that they will not compromise patients’ clinical status and safety, nor of operators or, if applicable, of third parties, when used for the intended purposes and under the conditions indicated. The possible existing risks must be acceptable when compared to the benefit provided to patients. Risks must be mitigated to a degree compatible with the protection of people’s health and safety.

2. The solutions adopted by manufacturers for healthcare product designs and production must be adjusted to up-to-date technological principles.

When finding the most adequate solutions, manufacturers must apply the following principles, in the following order:

a) when possible, eliminate or mitigate risks (safety inherent to the design and production);

b) adopt suitable protective measures, including alarms, if necessary, when risks could not be eliminated;

c) inform operators about residual risks due to incomplete efficacy of the adopted protective measures.

3. Healthcare products must deliver the performance attributed by the manufacturer and must carry out their functions as specified.

4. The characteristics and performance of healthcare products must not be modified in a degree that may compromise patients’ or users’ clinical status and safety – nor, if applicable, those of third parties – as long as the product has not expired and is used under normal conditions.

5. Healthcare products must be designed, manufactured, and packaged in a way that their characteristics and performance will not be modified during storage and transportation, considering their intended use, instructions, and data provided by the manufacturer.

6. Any undesirable secondary effect must constitute an acceptable risk related to the desired performance.

II. Requirements related to Design and Production
7. Chemical, Physical and Biological Properties

7.1. Healthcare products must be designed and manufactured in order to guarantee the characteristics and performance mentioned in item I (General Requirements), with special attention to:

a) selection of the used materials, paying particular attention to their toxicity and, if applicable, their inflammability;

b) compatibility among the used materials and between the materials and biological tissues, body cells and fluids, taking into account the medical device's intended use.

7.2. Considering the product's intended use, healthcare products must be designed, manufactured and packaged in a way that risks caused by contaminants and residues are mitigated for patients and for those involved in transportation, storage and use of the product. Special attention must be paid to exposed tissues and to the duration and frequency of such exposure.

7.3. Healthcare products must be designed and manufactured in a way that they can be used in a completely safe manner with the materials, substances and gases they have contact during their normal use and customary procedures. In cases that healthcare products are used for administration of medications, they must be designed and manufactured compatibly with the medications mentioned in the provisions and restrictions that govern such products and their use must be permanently adjusted to their intended purpose.

7.4. Healthcare products must be designed and manufactured in order to mitigate to the minimal possible level the risks derived from their released substances.

8. Infection and Microbial Contamination

8.1. Healthcare products and their manufacturing processes must be designed in order to eliminate or mitigate the risk of infection to patients, users, operators or third parties involved.

8.2. Tissues of animal origin must proceed from animals that had been submitted to adequate veterinary controls and follow-ups according to the use for which these tissues are intended. Tissues, cells and substances of animal origin must be transformed, preserved, analyzed and handled in a way that the highest guarantee levels of safety are provided. Aiming to provide guarantees against viruses and other transmissible agents, acknowledged methods of viral elimination or inactivation must be used during the manufacturing process.

8.3. Healthcare products distributed sterile must be designed, manufactured and packaged in a single-use packaging or according to appropriate procedures so that they may be still sterile when commercialized, and that they maintain this quality under the indicated storage and transportation conditions, until the protective packaging that guarantees their sterility is violated or opened.

8.4 Healthcare products distributed sterile must be manufactured and sterilized using appropriate validated methods.

8.5. Healthcare products that must be sterilized must be manufactured under adequately controlled conditions (e.g. those related to atmospheric conditions).
8.6. Packaging systems designed for non-sterile healthcare products must maintain the product in the indicated state of cleanliness without deterioration. If the product needs to be sterilized before use, the risk of microbial contamination must be mitigated. The packaging system must be appropriate for the sterilization method indicated by the manufacturer.

8.7. The packaging and labeling of healthcare products must allow identical or similar products to be clearly distinguished by a simple look at their presentation form, sterile and non-sterile.

9. Properties related to Production and Environment

9.1. When a healthcare product is intended to be used in combination with other products or equipment, the combination, including its connection system, must be safe and must not modify the indicated performance. Any restriction to use must be indicated in labels or instructions for use.

9.2. Healthcare products must be designed and manufactured in order to eliminate or mitigate:

a) risks of injuries caused by their physical characteristics, including the ratio of volume/pressure, their dimension and, if applicable, their ergonomic features;

b) risks related to reasonably predictable atmospheric conditions, such as magnetic fields, external electric influences, electrostatic discharges, pressure, temperature, or variations of pressure and acceleration;

c) risks of reciprocal interference with other products normally used for diagnosis or therapy;

d) risks resulting from the aging of the materials used or from the loss of accuracy of any mechanism or control, in case of impossibility of maintenance or calibration.

9.3. Healthcare products must be designed and manufactured in order to mitigate risks of fire or explosion, if used under normal conditions. Special attention must be paid to products exposed to substances or gases that are inflammable or that are favorable to combustion.

10. Products with Measuring Functions

10.1. Healthcare products with measuring functions must be designed and manufactured in order to provide sufficient measuring stability and accuracy within the adequate range for the product’s intended use. The accuracy range must be provided by the manufacturer.

10.2. Based on the product’s intended use, measuring, control, or display scales must be designed to facilitate their reading.

11. Protection against Radiation

11.1. General Requirements

11.1.1. Healthcare products must be designed and manufactured in order to mitigate to the minimal possible level, compatibly with their intended use, any exposure of patients, operators and third parties to radiation, without limiting the application of adequate levels of radiation
indicated for therapeutic or diagnostic purposes.

11.2. Intentional Radiation

11.2.1. When healthcare products are designed to emit dangerous levels of radiation required for a therapeutic medical purpose and/or a specific diagnosis, the benefit of which is considered superior to the risks inherent to emissions; such emissions must be controlled by the operator. These products must be designed and manufactured in order to ensure repeatability and tolerance of pertinent variable parameters.

11.2.2. When healthcare products are intended to emit potentially dangerous radiation, visible and/or invisible, they must be equipped with visual and/or audible indicators of such emission.

11.3. Non-Intentional Radiation

11.3.1. Healthcare products must be designed and manufactured in order to mitigate to the minimal possible level any exposure of patients, operators and third parties to the emission of non-intentional, spurious or scattered radiation.

11.4. Instruction for Use

11.4.1. The instructions for use of healthcare products that emit radiation must include detailed information on the characteristics of such emission, the patients’ and operators’ means of protection and the ways to avoid erroneous handling and to eliminate risks resulting from installation.

11.5. Ionizing Radiation

11.5.1. Healthcare products that emit ionizing radiation must be designed and manufactured in a way that the quantity and the quality of such emission can be regulated and controlled according to the product's intended use.

11.5.2. Healthcare products that emit ionizing radiation for radiologic diagnosis must be designed and manufactured in order to ensure good quality of imaging and/or outcomes with minimal exposure of patients and operators to the radiation, according to the medical intended use of the product.

11.5.3. Healthcare products that emit ionizing radiation for radiotherapy must be designed and manufactured in order to allow reliable vigilance and control of the administered doses, of the type of ray beam used, of the energy and of the type of radiation.

12. Requirements for Medical Products Connected to or Equipped with a Power Source

12.1. Healthcare products that incorporate programmable electronic systems must be designed in order to ensure repeatability, reliability and efficacy of these systems in accordance with their intended use. In case of conditions of first defect in the system, the ways to eliminate or mitigate the consequent risks as much as possible must be provided.

12.2. Healthcare products that have an internal power source on which patients’ safety depends must be provided with means that allow the power source status to be determined.
12.3. Healthcare products connected to an external power source on which patients’ safety depends must include a warning system that indicates any power source failure.

12.4. Healthcare products used to monitor one or more clinical parameters of a patient must have appropriate warning systems in order to alert the operator about situations that may cause risky conditions or that may worsen patient’s health status.

12.5. Healthcare products must be designed and manufactured in order to mitigate the risks of generating electromagnetic fields that may damage the operation of other products in the vicinity.

12.6. Protection against electrical risks

12.6.1. Healthcare products must be designed and manufactured in order to eliminate the risks of accidental electric shocks when correctly installed and used under normal or first defect conditions.

12.7. Protection against mechanical and thermal risks

12.7.1. Healthcare products must be designed and manufactured in a way that patients and operators are protected against mechanical risks resulting from, for example, strength, stability or moving pieces.

12.7.2. Healthcare products must be designed and manufactured to mitigate to the minimal possible level risks resulting from vibrations caused by the products, taking into account the technological progress and the availability of means to reduce such vibrations, especially in their origin, unless these are part of the product specifications.

12.7.3. Healthcare products must be designed and manufactured to mitigate to the minimal possible level risks resulting from the emission of noise, taking into account the technological progress and the availability of means to reduce such noises, especially in their origin, unless these are part of the desired performance.

12.7.4. Terminals and connectors of healthcare products for electric, hydraulic, pneumatic or gas energy that have to be handled by an operator must be designed and manufactured to mitigate any risk to the minimal possible level.

12.7.5. When used under normal conditions, accessible parts of healthcare products and their surroundings may not reach temperatures that represent hazard (excluding those parts or zones designed to provide heat or to reach certain temperatures).

12.8. Protection against risks that power sources or administration of substances may pose to patients

12.8.1. Healthcare products with the intended use of supplying energy or administering substances to patients must be designed and manufactured in a way that the flow can be regulated and maintained with sufficient accuracy in order to ensure patient’s and operator’s safety.

12.8.2. Healthcare products must be provided with means that allow any inaccuracy to be avoided and/or indicated in case of deficit of energy or substance that may cause hazard. Healthcare products must be equipped with adequate means that avoid accidental releases of
dangerous levels of energy and/or substances.

12.9. The function of controls and indicators must be clearly indicated in healthcare products.

12.9.1. Should a healthcare product come along with its necessary instructions for use or along with its adjusting or control indications by using a visual system, such information must be intelligible to the operator and, if necessary, to the patient or user.