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COLLEGIATE BOARD RESOLUTION - RDC No. 848, OF MARCH 6, 2024

Provides for the essential safety and performance requirements applicable to medical devices and in vitro diagnostic (IVD) medical devices.

THE COLLECTIVE BOARD OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the use of the powers conferred on it by art. 15, III and IV, combined with art. 7th, III and IV of Law No. 9,782, of January 26, 1999, and art. 187, VI, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC nº 585, of December 10, 2021, resolves to adopt the following Resolution, as resolved in a meeting held on March 6, 2024, and I, Director- President, I order its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Object

Art. 1 This Resolution aims to define the essential principles of safety and performance as general criteria that must be met by medical devices and medical devices for in vitro diagnosis (IVD).

§1 Compliance with essential safety and performance principles must be maintained throughout the life cycle of medical devices and IVD.

§2 Medical devices and IVD must be:

I - designed to be safe and effective, in accordance with the essential principles of safety and performance;

II - manufactured to maintain the design characteristics; It is

III - used as determined in the project.

§3 Verification of compliance of medical devices and IVD with essential requirements is carried out by the health surveillance authority during the inspection of Good Manufacturing Practices, the registration or notification of products with Anvisa or the health inspection of products.

Section II

Scope of application

Art. 2 This Resolution applies to all medical devices and IVD and is intended to identify and describe essential safety and performance principles that must be taken into account during the design and manufacturing processes.

Single paragraph. Depending on the device, some of the principles may not apply essential for safety and performance, and justifications must be provided for their exclusion.

Section III

Definitions

Art. 3 For the purposes of this Resolution, the following definitions will apply:

I - Risk analysis: systematic use of available information to identify hazards and calculate risk;

II - Clinical evaluation: set of continuous activities that use scientifically sound methods for the evaluation and analysis of clinical data in order to verify the safety and clinical performance of the medical device when used as intended by the manufacturer;

III - Risk assessment: procedure based on risk analysis to determine whether it was tolerable risk exceeded;

IV - Benefit: positive impact or desirable result of the use of a medical device on an individual's health status, or a positive impact on patient management or public health;

V - Life cycle: all phases of the life of a medical device, from initial conception to decommissioning and final disposal;

VI - Risk control: process in which decisions are made and measures are implemented to reduce or maintain risks within the levels specified by the manufacturer without compromising the risk-benefit ratio;

VII - Clinical data: safety and/or performance information that is generated from the clinical use of a medical device;

VIII - Damage: injury or harm to people's health, or damage to property or the environment environment;

IX - Analytical performance of a medical device for in vitro diagnosis: ability to an in vitro diagnostic medical device for detecting or measuring a specific analyte;

X - clinical performance of an in vitro diagnostic medical device: capacity of an in vitro diagnostic device to produce correlated results with a specific clinical condition or physiological state, according to the target population and the user provided;

XI - Clinical performance of a medical device: ability of a medical device to achieve clinical results in their intended purpose as claimed by the manufacturer;

XII - Performance of an in vitro diagnostic medical device: ability of an in vitro diagnostic medical device to achieve the intended purpose or use as claimed by the manufacturer;

XIII - Performance: ability of a medical device to achieve its intended purpose according to the manufacturer's declaration, which may include both clinical and technical aspects;

XIV - Risk determination: general process that comprises a risk analysis and a risk assessment;

XV - Effective: capacity of a medical device or medical device for in vitro diagnosis to provide clinically significant results in a significant portion of the target population;

XVI - Stability: ability of a medical device and medical device for in vitro diagnosis to maintain its characteristics and/or performance unchanged over a certain period of time, in accordance with previously established appropriate conditions;

XVII - State of the art: developed stage of technical capacity at a given moment in relation to products, processes and services, based on relevant consolidated discoveries of science, technology and experience;

XVIII - Clinical evidence for an in vitro diagnostic medical device: all information that supports scientific validity and performance for its use as intended by the manufacturer.

XIX - Clinical evidence: clinical data and the clinical evaluation report relating to a device doctor;

XX - Risk management: systematic application of policies, procedures and management practices to the tasks of analysis, evaluation, control and monitoring of risks associated with a given product or process;

XXI - Clinical investigation: systematic investigation or study involving one or more human beings, carried out to evaluate the safety and/or clinical performance and/or effectiveness of a medical device;

XXII - Danger: potential source of damage;

XXIII - Shelf life or maximum storage period: maximum period of time until the expiration date during which a medical device in its original packaging maintains its stability under the storage conditions specified by the manufacturer;

XXIV - Adequately reduce risks: reducing risks to a determined acceptable level by the manufacturer and the regulatory authority without harming the relationship between benefits and risks;

XXV - Clinical evaluation report: document that contains the evaluation and analysis of clinical data relating to the medical device, to verify the clinical safety and performance of the device when used as intended by the manufacturer;

XXVI - Risk: combination of the probability of damage occurring and the severity of that damage;

XXVII - Label: written, printed or graphic information appearing on the device itself, on the packaging of each unit or on the packaging of several devices;

XXVIII - Safety: absence of unacceptable risks;

XXIX - Dangerous situation: circumstance where people, property or the environment is/are exposed to one or more hazards;

XXX - Normal use: operation, including routine inspection and adjustments by any user, and stand-by, in accordance with the instructions for use or in accordance with generally accepted practice for medical devices and in vitro diagnostic medical devices supplied without instructions for use;

XXXI - Intended use/intended purpose: the use for which a device is intended, in in accordance with the information declared by the manufacturer in the clinical evaluation;

XXXII - Useful life: period of time specified by the manufacturer during which the medical device and in vitro diagnostic medical device is expected to maintain safe and effective use, which can be determined by stability;



§1 The benefit defined in section IV may include:

I - positive impact on clinical results, patient quality of life and results related to diagnosis;

II - positive impact of diagnostic products on clinical results; or

III - positive impact on public health.

§2 The clinical performance of a medical device for in vitro diagnostics may include:

I - diagnostic sensitivity and specificity based on clinical or physiological status known to the individual; It is

II - negative and positive predictive values depending on the prevalence of the disease.

§3 The performance of a medical device for in vitro diagnosis defined in item XII consists of the analytical performance and, when applicable, the clinical performance that support the intended use of the medical device for in vitro diagnosis.

§4 The capacity of a medical device or in vitro diagnostic medical device is assessed in situations where the medical device or in vitro diagnostic medical device is used for its intended uses and conditions of use and accompanied by appropriate instructions for use and warnings against unsafe use.

§5º The adequate risk reduction defined in item XXIV must be:

I - reduction to as low a risk as reasonably possible;

II - reduction to a risk as low as reasonably achievable; or

III - risk reduction as much as possible

§6 The normal use defined in section XXX should not be confused with the intended use, although both include the concept of use as intended by the manufacturer, the intended use focuses on the medical purpose, while normal use incorporates not only the medical purpose , but also maintenance, transportation and other aspects.

§7º Usage error may occur in normal use defined in section XXX.

§8 Medical devices and in vitro diagnostic medical devices that can be used safely without instructions for use are exempt from having instructions for use by some competent authorities.

CHAPTER II

SAFETY AND PERFORMANCE OF MEDICAL DEVICES

Section I

General Essential Principles

Art. 4 This Resolution describes the fundamental design and manufacturing requirements, called "essential safety and performance principles", to ensure the safety and performance of a medical device or IVD.

§1 The manufacturer of a medical device or IVD must design and manufacture a product that is safe and that works as expected in the project throughout its life cycle.

§2 The design and manufacturing activities of medical devices and IVD must be controlled by the manufacturer's quality management system.

§3 The compliance of the medical device or IVD with all applicable essential principles must be demonstrated in the product's technical dossier or files relating to the manufacturing and/or validation process, available from the manufacturer.

Section II

Essential Principles Applicable to All Medical Devices and IVD

Art. 5 The essential design and manufacturing principles listed in this section are applicable to medical devices and IVDs.

Subsection I

General considerations

Art. 6 Medical devices and IVD must meet the following requirements:

I - achieve the performance predicted by the manufacturer;

II - be designed and manufactured so that they are suitable for the intended purpose under the established conditions of use;

III - be safe;

IV - function as expected;

V - have acceptable risks compared to the benefits for the patient;

VI - not compromise the clinical condition or safety of patients or other people.

Art. 7 Manufacturers must establish, implement, document and maintain a risk management system to ensure the ongoing quality, safety and performance of the medical device and the IVD.

§1 Risk management must be understood as a continuous process throughout the entire life cycle of a medical device and IVD, with the need for systematic and periodic updating.

§2 When carrying out risk management, manufacturers must:

I - establish and document a risk management plan for each medical device and IVD;

- identify and analyze the known and predictable hazards associated with each medical device and IVD;

II - estimate and evaluate the risks associated with and occurring during the intended use and reasonably foreseeable misuse;

III - eliminate or control the risks mentioned in section III in accordance with the requirements of articles 10 and 11 below;

IV- evaluate the impact of information from the production and post-production phases on the overall risk, the determination of the risk-benefit and the acceptability of the risk, including the impact of previously unknown hazards or dangerous situations, the acceptability of the risks estimates arising from a dangerous situation and changes to the state of the art; It is

V - based on the assessment of the impact of the information mentioned in section V, if necessary, change control measures in accordance with the requirements indicated in articles 9 and 10.

Art. 8 The risk control measures adopted by manufacturers for the design and manufacture of the medical device and the IVD must adapt to safety principles, taking into account the state of the art.

§1 When risk reduction is necessary, manufacturers must control them so that the residual risk associated with each hazard and the overall residual risk are considered acceptable.

§2 Manufacturers must select the most appropriate solutions, in this order of priority:

I - adequately eliminate or reduce risks through safe design and manufacturing;

II - as appropriate, adopt appropriate protection measures, with the inclusion of alarms if necessary, in relation to risks that cannot be eliminated; It is

III - provide information on safety: warnings, precautions and contraindications and, as appropriate, training for users.

Art. 9th. The manufacturer must inform users of any relevant residual risk.

Art. 10. When eliminating or reducing risks related to use, the manufacturer must:

I - adequately reduce the risks related to the characteristics of the medical device and IVD and the intended use environment of these devices; It is

II - consider technical knowledge, experience, education, training and environment of use and, as applicable, the medical and physical conditions of the intended users.

Art. 11. The characteristics and performance of a medical device or IVD must not be impaired to the point of compromising the health or safety of the patient, the user, and when applicable, other people during the useful life of the device, specified by the manufacturer , when the medical device or IVD is subjected to the stress that may occur during normal conditions of use and must be properly maintained and calibrated, if applicable, in accordance with the manufacturer's instructions.

Art. 12. Medical devices and IVD must be designed, manufactured and packaged in such a way that their characteristics and performance, including integrity, product cleanliness and sterility, when applicable, are maintained for their use in accordance with the intended use, and are not harmed by transport and storage such as: impacts, vibrations and variations in temperature and humidity, taking into account the instructions and information provided by the manufacturer.

Single paragraph. The performance, safety and sterility, where applicable, of the device medical device or IVD must be maintained throughout the shelf life specified by the manufacturer.

Art. 13. Medical devices and IVD must have acceptable stability during the following periods:

I - period of validity;

II - time of use after opening, including after being installed on the instrument in case of IVD; It is

III - transportation or shipping, including samples in the case of IVD.

Art. 14. All known and predictable risks, and possible undesirable side effects, must be minimized and acceptable when compared to the benefits arising from the performance achieved by the device during the intended conditions of use, taking into account the state of the art.

Subsection II

Clinical Assessment

Art. 15. The indication and purpose of use, performance and safety of a medical device must be supported by relevant clinical data, obtained through a clinical evaluation of the medical device.

Art. 16. The clinical evaluation must analyze clinical data with scientific validity to prove the existence of a favorable risk-benefit relationship of the medical device or IVD through one or more of the following documents:

I - clinical evaluation report(s) containing critical analysis of relevant scientific literature, whose results present an acceptable level of evidence in the hierarchy used by evidence-based medicine; It is

II - clinical investigation report(s) (for IVD, performance evaluation reports clinical).

§1 The clinical evaluation report must be in line with the state of the art, current knowledge, be scientifically sound and cover all aspects of the intended purpose of the medical device(s) contained within the scope of the clinical assessment.

§2º The clinical evaluation report must include favorable data and unfavorable data, summarizing them appropriately, through identification, evaluation, analysis and referencing.

§3 The update of the clinical evaluation report must be carried out periodically, the frequency of which must be established by the manufacturer considering the existence of significant risks and when changes occur that impact the performance and/or safety of the device.

Art. 17. Clinical investigations of medical devices and IVD must be carried out in accordance with with good clinical practices.

Single paragraph. Clinical investigations conducted in Brazil must meet the specific Anvisa regulations.

Art. 18. Clinical investigations of a specific medical device are mandatory when existing data, collected by the manufacturer and documented in the clinical evaluation report, are not sufficient to address the risk-benefit profile, claims and adverse events in order to demonstrate the compliance with the safety and performance principles applicable to this specific medical device.

Art. 19. Reports of clinical investigations conducted specifically with the medical device to be regularized with Anvisa must be presented, as a way of proving its safety and effectiveness, in the following situations:

I - Medical devices containing innovations in design, raw material, indication of use, among others, regardless of their risk class; It is

II - Medical devices of risk classes III and IV which, due to their unique nature and performance closely linked to the material design and manufacturing process, require safety and efficacy verification using clinical data specific to the medical device under evaluation.

Subsection III

Chemical, Physical and Biological Properties

Art. 20. In relation to the chemical, physical and biological properties of a medical device and IVD, special attention should be paid to:

I - choice of materials and substances used, mainly with regard to:

a) toxicity;

b) biocompatibility; It is

c) flammability;

II - impact of processes on the properties of materials and the final product;

III - when applicable, results of biophysical research or modeling whose validity has been previously demonstrated;

IV - mechanical properties of the materials used, reflecting, as appropriate, aspects such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;

V - surface properties;

VI - confirmation that the device meets all chemical and/or physical specifications and/or defined biological; It is

VII - combination of suitable materials for products composed of different materials and also the use of suitable materials according to the characteristics of the project and the indication of use.

Art. 21. Medical devices and IVD must be designed, manufactured and packaged in a way that minimizes the risk caused by contaminants and residues for users and patients, taking into account their intended purpose, as well as for the people involved in transportation, in storage and use of devices.

Single paragraph. Special attention must be paid to the tissues of users and patients exposed to the contaminants and residues mentioned in the caput, and to the duration and frequency of exposure.

Art. 22. Medical devices and IVD must be designed and manufactured in a way that adequately reduces the risks caused by the release of substances, including leaching and/or evaporation, degradation products, processing residues, among others.

Single paragraph. Special attention should be paid to the release or leaching of carcinogenic, mutagenic or reproductive toxic substances.

Art. 23. Medical devices and IVD must be designed and manufactured in a way that adequately reduces the risks arising from the unintentional entry of substances into the device, taking into account the device and the nature of the intended environment of use.

Art. 24. Medical devices and IVD and their manufacturing processes must be designed in such a way as to eliminate or adequately reduce the risk of infection for users and all other people who may come into contact with the device, and the design must:

I - allow easy and safe handling;

II - adequately reduce any microbial release from the medical device or IVD and/or microbial exposure during use;

III - avoid microbial contamination of the medical device and IVD or its contents; It is

IV - adequately reduce the risks of unintentional exposure.

Subsection IV

Sterilization and Microbial Contamination

Art. 25. When necessary, medical devices and IVD must be designed to facilitate the user to safely proceed with cleaning, disinfection, sterilization and re-sterilization, when applicable.

Art. 26. Medical devices and IVD that have a specific microbial status must have their microbiological specifications established in the project, which must be maintained throughout the product's validity period and under the conditions of use and packaging foreseen by the manufacturer.

Art. 27. Medical devices and IVD supplied sterile must be designed, manufactured and packaged in accordance with appropriate procedures in order to ensure that they are sterile when placed on the market and that, unless the packaging intended to maintain the sterile condition is damaged , remain sterile under the transport and storage conditions specified by the manufacturer until the packaging is opened at the place of use.

Single paragraph. It must be ensured that the end user has no doubts about the integrity of the packaging.

Art. 28. Medical devices and IVD specified as sterile must be processed, manufactured, packaged and sterilized using appropriate and validated methods.

Single paragraph. The maximum storage period of the aforementioned medical devices and IVD in the caput must be determined by validated methods.

Art. 29. Medical devices and IVD intended to be sterilized, by the manufacturer or user, must be manufactured and packaged in adequate and controlled environmental conditions and facilities.

Art. 30. Medical devices and IVD supplied in non-sterile conditions and intended to be sterilized before use must meet the following requirements:

I - the packaging system must minimize the risk of microbial contamination and must be appropriate, taking into account the sterilization method indicated by the manufacturer; It is

II - the sterilization method indicated by the manufacturer must be validated.

Art. 31. Medical devices and IVD placed on the market in both sterile and non-sterile conditions must have a label that clearly differentiates the versions.

Subsection V

Environmental Considerations and Conditions of Use

Art. 32. If the medical device or IVD is intended for use in combination with other medical devices or IVD and/or equipment, the entire assembly or system, including connections, must be safe and not impair the specified performance of the device(s) (s).

§1º Any known restriction applicable to these combinations must be indicated on the label and/or in the instructions for use.

§2º Any connections handled by the user, such as those intended for transfers of liquids or gases and electrical or mechanical couplings, must be designed and manufactured in such a way as to eliminate or adequately reduce all possible risks, including connection errors or dangers to the security.

Art. 33. Medical devices and IVD must be designed and manufactured taking into account the environment and conditions of intended use and in a way that adequately eliminates or reduces:

I - the risks of injury to users or other people related to their physical, ergonomic or usability characteristics;

II - the risks of user error arising from the design of the user interface, ergonomic or usability characteristics, and the anticipated environment of use of the medical device or IVD;

III - risks associated with external influences or reasonably predictable environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature and/or variations in pressure and acceleration;

IV - the risks associated with the use of the medical device or IVD when they come into contact with materials, liquids and substances, including gases, to which they are exposed under the intended conditions of use;

V - the risks associated with the possible negative interaction between the software and the environment information technology (IT) in which it works and interacts;

VI - risks to the environment arising from the accidental release of substances from the medical device or IVD during use, taking into account the device and the nature of the intended environment of use;

VII - the risk of misidentification of samples or data and the risk of erroneous results arising from confusion in the color and/or numerical coding of sample containers, removable parts and/or accessories used to perform the analysis, test or the planned test and other situations; It is

VIII - the risks of interference with other medical devices or IVD normally used in diagnosis, monitoring or treatment.

Art. 34. Medical devices and IVD must be designed and manufactured in a way that adequately eliminates or reduces the risks of fire or explosion during normal use and in a single failure condition.

Single paragraph. Special attention should be given to medical devices and IVDs whose intended use includes exposure to or association with flammable or explosive substances that may cause combustion.

Art. 35. Medical devices and IVD must be designed and manufactured in such a way that the adjustment, calibration and maintenance can be carried out safely and effectively.

§1 Specifically when maintenance is not possible, the risks of aging of materials, among others, must be reduced appropriately.

§2º Specifically when adjustment and calibration are not possible, the risks of loss of accuracy of any measuring or control mechanism must be reduced accordingly.

Art. 36. Medical devices and IVD intended for operation in conjunction with other devices or products must be designed and manufactured in such a way that interoperability and compatibility are reliable and safe.

Art. 37. Medical devices and IVDs must be designed and manufactured in a way that adequately reduces the risk of unauthorized access that would prevent them from functioning as intended or that would cause a security problem.

Art. 38. Any measuring, monitoring or reading scale of medical devices and IVD must be designed and manufactured in accordance with ergonomic and usability principles, taking into account the intended use, users and environmental conditions of intended use.

Art. 39. Medical devices and IVDs must be designed and manufactured in a way that facilitates their safe disposal or recycling, as well as the safe disposal or recycling of waste generated by the user, patient or other person.

Single paragraph. Instructions for use must identify safe disposal or recycling procedures and measures, when applicable.

Subsection VI

Protection Against Electrical, Mechanical and Thermal Risks

Art. 40. Medical devices and IVD must be designed and manufactured in a way to protect users against mechanical risks, such as those related to resistance to movement, instability and moving parts.

Art. 41. Medical devices and IVD must be designed and manufactured in a way to reduce adequately address the following risks:

I - risks arising from the vibrations they produce, taking into account technological progress and the resources available to limit vibrations, mainly at the source, unless the vibrations are part of the specified performance;

II - risks arising from the noise emitted, taking into account technological progress and resources available for noise reduction, mainly at the source, unless the noise is part of the specified performance; It is

III - risk related to the failure of any part of the device intended to be connected or reconnected before or during use.

Art. 42. The accessible parts of medical devices and IVD, except the parts or areas intended to provide heat or reach certain temperatures, and their surroundings must not reach potentially dangerous temperatures, under normal conditions of use.

Subsection VII

Active Medical Devices, IVD and Medical Devices Connected to Them

Art. 43. With regard to active medical devices and IVD, in the case of a single failure condition, appropriate measures must be adopted to eliminate or adequately reduce the resulting risks.

Art. 44. Medical devices and IVD in which patient safety depends on an internal energy source must have a means to determine the status of that source and an appropriate warning or indication in case the capacity of the energy source become critical.

Art. 45. Medical devices and IVD in which patient safety depends on a source external power supply must have an alarm system that indicates an eventual power failure.

Art. 46. Medical devices and IVD intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations that could cause death or serious deterioration of the patient's health status.

Art. 47. Medical devices and IVD must be designed and manufactured in a way to reduce adequately address the following risks:

I - risks of electromagnetic interference that could harm the functioning of any device or equipment installed in the intended environment; It is

II - risk of accidental electrical discharges to the user or any other person, both during normal use and in a single failure condition, provided that the devices are installed and maintained as per the manufacturer's instructions.

Art. 48. Medical devices and IVD must be designed and manufactured in a way that provides a satisfactory level of security against possible electromagnetic interference and that allows them to function as intended.

Subsection VIII

Medical Devices and IVDs that Incorporate Software or That Constitute in Themselves a Software as a Medical Device

Art. 49. Medical devices and IVD that incorporate programmable electronic systems, including software, or that constitute software in themselves as a medical device, must be designed to guarantee accuracy, reliability, precision, safety and performance in accordance with the intended use .

Single paragraph. If a single failure condition occurs, appropriate measures must be taken to eliminate or adequately reduce the resulting risks or compromised performance.

Art. 50. In the case of medical devices and IVD that incorporate software or that in themselves constitute software as a medical device, the software must be developed, manufactured and maintained in accordance with the state of the art, taking into account cycle principles development lifecycle, risk management, including information security, verification and validation.

Art. 51. Software intended to be used in conjunction with mobile platforms must be designed and developed taking into account the platform itself, including size, screen contrast, connectivity and memory, and external factors related to its use , including the variable environment with regard to light or noise level.

Art. 52. Manufacturers must indicate the minimum hardware requirements, the characteristics of information technology (IT) networks and the IT security measures, including protection against unauthorized access, necessary to run the software as intended.

Art. 53. The medical device and IVD must be designed, manufactured and maintained in a manner that provide an adequate level of cybersecurity against unauthorized access attempts.

Subsection IX

Medical Devices and IVD with Diagnostic or Measurement Function

Art. 54. Medical devices and IVD that have a diagnostic or measuring function, including monitoring, must be designed and manufactured in a way that provides, among other performance characteristics, accuracy, precision and stability sufficient for the intended purpose, based in appropriate scientific and technical methods.

§1 The manufacturer must indicate the limits of accuracy when applicable.

§2 Values expressed numerically must be in commonly accepted and standardized units of measurement whenever possible and users of the medical device or IVD must understand them.

§3 Aspects of safety, user familiarity and established clinical practice may justify the use of other recognized measurement units, although global convergence towards the use of internationally standardized measurement units is generally supported.

§4 The function of controls and indicators must be clearly specified on the medical device and IVD.

§5 Operating instructions or indication of operating or adjustment parameters of a medical device or IVD presented through a visual system must be understandable for the user and, as the case may be, for the patient.

Subsection

Label and Instructions for Use

Art. 55. Medical devices and IVD must be accompanied by the necessary information to specifically identify the device and its manufacturer.

§1 Each medical device and IVD must also be accompanied by safety and performance information relevant to the user, or any other person, or direct the user to such information, as appropriate.

§2 This information may appear on the body of the medical device or IVD, on the label or in the instructions for use, or be readily accessible by electronic means, when permitted, and must be easily understood by the intended user.

§3 The requirements for the label and instructions for use of medical devices and IVD determined in specific regulations must be observed.

Subsection XI

Radiation Protection

Art. 56. Medical devices and IVD must be designed, manufactured and packaged in such a way that the exposure of users, other people or, where applicable, patients, to radiation is adequately reduced in a manner compatible with the intended purpose, without, however, restrict application to specified levels suitable for diagnostic and therapeutic purposes.

Art. 57. The operating instructions for medical devices and IVD that emit dangerous or potentially dangerous radiation must contain detailed information about the nature of the radiation emitted, the means of protecting users, other people or, as the case may be, patients, and the ways to avoid misuse and adequately reduce the risks inherent to transportation, storage and installation.

Art. 58. When medical devices and IVD are intended to emit dangerous or potentially dangerous radiation, they must be equipped, when possible, with visual indicators and/or audible warnings of these emissions.

Art. 59. Medical devices and IVD must be designed and manufactured in a way that adequately reduces the exposure of users, other people, or, where applicable, patients, to the emission of unintentional, diverted or scattered radiation.

Single paragraph. When possible and appropriate, methods should be selected that reduce radiation exposure to users, other people or, where applicable, patients, who may be affected.

Art. 60. In the case of medical devices and IVD that emit dangerous or potentially dangerous radiation and that require installation, information regarding acceptance and performance tests, acceptance criteria and the maintenance procedure must be specified in the operating instructions.

Art. 61. When medical devices and IVD are intended to emit dangerous or potentially dangerous radiation, which may reach the user, patient or other person, they must be designed and manufactured in a way that guarantees that the quantity, geometry, distribution (or quality) of energy and other essential characteristics of the emitted radiation can be adequately controlled and adjusted and, as appropriate, monitored during use.

Single paragraph. These medical devices and IVD must be designed and manufactured so as to ensure reproducibility of relevant variable parameters with an acceptable tolerance.

Subsection XII

Protection Against Risks Associated with Manufacturer-Intended Medical Devices and IVDs for Use by Laymen

Art. 62. Medical devices and IVD intended for use by laypeople must be designed and manufactured in such a way that they perform adequately for the intended use or purpose, taking into account the skills and means available to lay users and the influence resulting from variations in the lay user's technique or the environment, which can be reasonably predictable.



Single paragraph. The information and instructions provided by the manufacturer must be easy for laypeople to understand and apply when using the medical device or IVD and interpreting the results.

Art. 63. Medical devices and IVD intended for use by lay people must be designed and manufactured in such a way as to:

I - ensure that the medical device and IVD can be used safely and accurately by the user, in accordance with the instructions for use; It is

II - adequately reduce the risk of error on the part of the user when handling the device doctor or IVD and, if applicable, in the interpretation of the results.

Single paragraph. When the risks associated with the interpretation of instructions for use cannot be be reduced to acceptable levels, these risks can be mitigated by training.

Art. 64. Medical devices and IVD intended for use by lay people must, where appropriate, include means by which these:

I - can verify, at the time of use, whether the medical device or IVD performs intended by the manufacturer; It is

II - be warned if the medical device or IVD does not function as expected or does not provide a valid result.

Subsection XIII

Medical Devices and IVD Incorporating Material of Biological Origin

Art. 65. In relation to medical devices and IVD that contain tissues, cells or substances of animal, vegetable or bacterial origin or their derivatives, which are not viable or have become non-viable, the following provisions must apply:

I - depending on the case, taking into account the species of animal, tissues and cells of animal origin, or their derivatives, must come from animals that have been subjected to veterinary controls adapted to the intended use of the tissues; It is

II - the obtaining, processing, preservation, analysis and handling of tissues, cells and substances of animal origin, or their derivatives, must be carried out in order to guarantee the safety of patients, users and, as the case may be, , from other people.

Single paragraph. Safety regarding viruses and other communicable agents must be addressed by implementing up-to-date and validated methods for elimination or inactivation during the manufacturing process, unless use of these methods could cause unacceptable deterioration that would harm the medical device or IVD .

Art. 66. With regard to medical devices and IVD manufactured using biological substances other than those mentioned in article 69, the processing, conservation, analysis and handling of these substances must be carried out in a manner that guarantees the safety of patients, users and, as appropriate, other people, including those in the waste disposal chain.

Single paragraph. Safety regarding viruses and other transmissible agents must be addressed by appropriate collection methods and by implementing validated methods of elimination or inactivation during the manufacturing process.

Section III

Essential Principles Applicable to Medical Devices, Except IVD

Art. 67. The essential design and manufacturing principles enumerated in this Section are complementary to the essential principles enumerated in Section II.

Subsection I

Chemical, Physical and Biological Properties

Art. 68. With regard to the chemical, physical and biological properties of a medical device, special attention must be paid to the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking into account the intended purpose of the device and, when relevant, its absorption, distribution, metabolism and excretion.

Art. 69. Medical devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they come into contact during their intended use.

Art. 70. Medical devices that are intended to administer medicines must be designed and manufactured in such a way as to be compatible with the medicines in question, in accordance with the provisions and restrictions that regulate these medicines and in such a way that the performance of both medicines how much of the devices is maintained according to their respective indications and intended use.

Art. 71. Medical devices must be designed and manufactured in a way that adequately reduces the risks associated with the size and properties of particles that are released or may be released into the patient's or user's body, unless they come into contact with only with intact skin.

Single paragraph. Special attention should be paid to nanomaterials.

Subsection II

Radiation Protection

Art. 72. Medical devices that emit ionizing radiation intended for imaging examinations must be designed and manufactured in such a way as to achieve an image quality and/or result suitable for the intended medical purpose, although with the least possible exposure of the patient, user and other people to radiation.

Art. 73. Medical devices that emit ionizing radiation must be designed to allow accurate estimation (or monitoring), visualization, notification and recording of the dose of a treatment.

Subsection III

Specific Requirements for Implantable Medical Devices

Art. 74. Implantable medical devices must be designed and manufactured in a way that adequately eliminate or reduce risks associated with medical treatment.

Art. 75. Active programmable implantable medical devices must be designed and manufactured in a way that allows unequivocal identification of the device without the need for surgical intervention.

Subsection IV

Protection Against the Risks posed by Medical Devices that Administer Energy or Substances They can offer the patient or user

Art. 76. Medical devices intended to administer energy or substances to the patient must be designed and manufactured in such a way that it is possible to adjust and maintain the administered quantity with sufficient accuracy to guarantee the safety of the patient, the user and others people.

Art. 77. Medical devices must be equipped with means to prevent and/or indicate any inappropriate amount of energy or substances administered, which could represent a danger.

Single paragraph. Devices must incorporate suitable means to reduce adequately eliminate the risk of accidental release of dangerous levels of energy or substances.

Subsection V

Medical Devices That Incorporate a Substance Considered a Medicine or Drug

Art. 78. When a medical device incorporates as an integral part a substance that, if used separately, can be considered a medicine or drug, and that can act in the body as an auxiliary to the medical device, the safety and performance of the device must be verified. medical device as a whole, as well as the identity, safety, quality and efficacy of the substance present in the combined product.

Section IV

Essential Principles Applicable to IVD

Art. 79. The essential design and manufacturing principles enumerated in this Section are complementary to the essential security and performance principles enumerated in Section II.

Subsection I

Chemical, Physical and Biological Properties

Art. 80. Regarding the chemical, physical and biological properties of IVD, the possibility of compromising analytical performance due to physical and/or chemical incompatibility between the materials used and the samples, the analyte or the marker to be considered must be considered. be detected and measured, taking into account the intended purpose of the device.

Subsection II

Performance Characteristics

Art. 81. IVDs must achieve the analytical and clinical performance declared by the manufacturer that is applicable to the intended use or purpose, taking into account the target patient population, users and intended use environment.

§1 Performance characteristics must be established by appropriate methods, validated and updated.

§2 Analytical performance includes, among others:

I - traceability of calibrators and controls;

II - measurement accuracy (accuracy and precision);

III - analytical sensitivity/detection limit;

IV - analytical specificity;

V - measurement interval/range; It is

VI - sample stability.

§3 Clinical performance must be determined by clinical or diagnostic sensitivity, clinical or diagnostic specificity, positive predictive value, negative predictive value, likelihood ratios and expected values in normal and affected populations.

§4 Validated control procedures must assure the user that the IVD has the intended performance and therefore the results are suitable for the intended use.

Art. 82. When the performance of an IVD depends on the use of calibrators or control materials, the traceability of values assigned to these calibrators or control materials must be guaranteed by available reference measurement procedures or by available higher order reference materials (primary standard).

Art. 83. Whenever possible, values expressed numerically must be in units commonly accepted, standardized, and understood by IVD users.

Art. 84. The performance characteristics of the IVD must be evaluated according to the intended purpose, which must include:

I - intended user: layman or professional;

II - intended use environment: patient's home, emergency units, ambulances, health care centers, laboratory; It is

III - target populations: pediatric, adult, pregnant women, people with signs and symptoms of a specific disease, patients in the process of differential diagnosis, blood donors, among others.

§1 The populations evaluated must represent, as appropriate, diverse groups from an ethnic, gender and genetic point of view, so that they are representative of the populations for which the device is intended.

§2 In relation to infectious diseases, it is recommended that the selected populations have similar prevalence rates.

CHAPTER III

FINAL AND TRANSITIONAL PROVISIONS

Art. 85. 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 applicable civil, administrative and criminal responsibilities.

Art. 86. The Resolution of the Collegiate Board of Directors is revoked - RDC nº 546, of August 30, 2021, published in the Official Gazette of the Union nº 165, of August 31, 2021, Section 1, page. 131.

Art. 87. Protocols of petitions for the regularization of medical devices and medical devices for in vitro diagnosis (IVD) filed before the period of validity of this Resolution will be accepted with the essential safety and effectiveness requirements defined in the Resolution of the Collegiate Board - RDC no. 546, of August 30, 2021.

Art. 88. This Resolution comes into force 180 (one hundred and eighty) days after its publication.

ANTONIO BARRA TORRES
CEO

This content does not replace that published in the certified version.