COLLEGIATE BOARD RESOLUTION – RDC No. 848 OF 6 MARCH 2024

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

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, and Article 7, items III and IV of Law no. 9,782 of 26 January 1999, and item VI, paragraph 1 of Article 187 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Resolution, as decided upon in a meeting held on 6 March 2024, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

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

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

Paragraph 2. Medical devices and IVD medical devices 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; and

III – used as determined in the design.

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

Section II

Scope of Application

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

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

Section III

Definitions

Article 3. For the purposes of this Resolution, the following definitions shall 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 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 tolerable risk has been 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;

IX – Analytical performance of a medical device for *in vitro* diagnosis: ability of an *in vitro* diagnostic medical device to detect or measure a specific analyte;

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

XI – Clinical performance of a medical device: ability of a medical device to achieve clinical results in its 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: ability of a medical device or *in vitro* diagnosis medical device to provide clinically significant results in a significant portion of the target population;

XVI – Stability: ability of a medical device and an *in vitro* diagnosis medical device 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 medical device;

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 efficacy of a medical device;

XXII – Hazard: 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 – Adequate risk reduction: reducing risks to an acceptable level determined 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 – Hazardous situation: circumstance where people, property, or the environment is 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 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 are expected to maintain safe and effective use, which can be determined by stability.

Paragraph 1. The benefit defined in item 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.

Paragraph 2. The clinical performance of an *in vitro* diagnostic medical device may include:

I – diagnostic sensitivity and specificity based on the individual known clinical or physiological status; and

II – negative and positive predictive values due to the prevalence of the disease.

Paragraph 3. The performance of an *in vitro* diagnostic medical device defined in item XII consists of the analytical performance and, when applicable, the clinical performance that support the intended use of the *in vitro* diagnostic medical device.

Paragraph 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.

Paragraph 5. The adequate risk reduction defined in item XXIV must be:

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

II – reduction to a risk as low as reasonably feasible; or

III – risk reduction as much as possible

Paragraph 6. The normal use defined in item 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.

Paragraph 7. Usage error may occur in normal use defined in item XXX.

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

CHAPTER II

SAFETY AND PERFORMANCE OF MEDICAL DEVICES

Section I

General Essential Principles

Article 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 medical device.

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

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

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

Section II

Essential Principles Applicable to All Medical Devices and IVD Medical Devices

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

Subsection I

General Considerations

Article 6. Medical devices and IVD medical devices 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 – work 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.

Article 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 medical device.

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

Paragraph 2. When carrying out risk management, manufacturers must:

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

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

III – estimate and evaluate the risks associated with and occurring during the intended use and reasonably predictable misuse;

IV – eliminate or control the risks referred to in item III in accordance with the requirements of articles 10 and 11 below;

V – evaluate the impact of information from production and post-production phases on the overall risk, the determination of risk-benefit and acceptability of risk, including the impact of previously unknown hazards or dangerous situations, the acceptability of expected risks arising from a hazardous situation and alterations to the state of the art; and

VI – based on the assessment of the impact of the information referred to in item V, if necessary, change control measures in accordance with the requirements provided for in articles 9 and 10.

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

Paragraph 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.

Paragraph 2. Manufacturers must select the most appropriate solutions, in the following 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; and

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

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

Article 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 medical device and the intended use environment of these devices; and

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

Article 11. The characteristics and performance of a medical device or IVD medical device 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 medical device 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.

Article 12. Medical devices and IVD medical devices 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 transportation and storage, for example: impacts, vibrations, and variations in temperature and humidity, taking into account the instructions and information provided by the manufacturer.

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

Article 13. Medical devices and IVD medical devices 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 medical devices; and

III – transportation or shipping, including samples in the case of IVD medical devices.

Article 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, considering the state of the art.

Subsection II

Clinical Evaluation

Article 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.

Article 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 medical device 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; and

II – clinical investigation report(s) (for IVD medical devices, clinical performance evaluation reports).

Paragraph 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 evaluation.

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

Paragraph 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.

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

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

Article 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 to demonstrate compliance with the safety and performance principles applicable to this specific medical device.

Article 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 efficacy, in the following situations:

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

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

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

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

a) toxicity;

b) biocompatibility; and

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 and/or biological specifications defined; and

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

Article 21. Medical devices and IVD medical devices must be designed, manufactured and packaged in a way that minimizes the risk caused by contaminants and residues for users and

patients, considering their intended purpose, as well as for the people involved in transportation, storage, and use of the devices.

Sole paragraph. Special attention must be paid to the tissues of users and patients exposed to the contaminants and residues referred to in the caption of this article, and to the duration and frequency of exposure.

Article 22. Medical devices and IVD medical devices 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.

Sole paragraph. Special attention should be paid to the release or leaching of carcinogenic, mutagenic substances, or substances that are toxic for reproduction.

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

Article 24. Medical devices and IVD medical devices 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 medical device and/or microbial exposure during use;

III – avoid microbial contamination of the medical device and IVD medical device or its contents; and

IV – adequately reduce the risks of unintentional exposure.

Subsection IV

Sterilization and Microbial Contamination

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

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

Article 27. Medical devices and IVD medical devices 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 transportation and storage conditions specified by the manufacturer until the packaging is opened at the place of use.

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

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

Sole paragraph. The maximum storage period of the medical devices and IVD medical devices referred to in the caption of this article must be determined by validated methods.

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

Article 30. Medical devices and IVD medical devices 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, considering the sterilization method indicated by the manufacturer; and

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

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

Subsection V

Considerations on the Environment and Conditions of Use

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

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

Paragraph 2. 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 hazards to safety.

Article 33. Medical devices and IVD medical devices must be designed and manufactured considering the foreseen environment and conditions of 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 user interface design, ergonomic or usability characteristics, and the foreseen environment of use of the medical device or IVD medical device;

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 medical device 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 information technology (IT) environment in which it works and interacts;

VI – risks to the environment arising from the accidental release of substances from the medical device or IVD medical device during use, considering 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 assay, and other situations; and

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

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

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

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

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

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

Article 36. Medical devices and IVD medical devices 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.

Article 37. Medical devices and IVD medical devices 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 safety problem.

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

Article 39. Medical devices and IVD medical devices 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.

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

Subsection VI

Protection Against Electrical, Mechanical, and Thermal Risks

Article 40. Medical devices and IVD medical devices 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.

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

I – risks arising from the vibrations they produce, considering 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, considering technological progress and the resources available for noise reduction, mainly at the source, unless the noise is part of the specified performance; and

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

Article 42. The accessible parts of medical devices and IVD medical devices, 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 Medical Devices, and Medical Devices Connected to Them

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

Article 44. Medical devices and IVD medical devices in which case 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 becomes critical.

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

Article 46. Medical devices and IVD medical devices 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.

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

I – risks of electromagnetic interference that could harm the functioning of any device or equipment installed in the intended environment; and

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 in accordance with the manufacturer's instructions.

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

Subsection VIII

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

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

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

Article 50. In the case of medical devices and IVD medical devices 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, considering principles of lifecycle development, risk management, including information security, verification, and validation.

Article 51. Software intended to be used in conjunction with mobile platforms must be designed and developed considering the platform itself, including size, screen contrast, connectivity, and memory, as well as external factors related to its use, including the variable environment regarding light or noise level.

Article 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.

Article 53. Medical devices and IVD medical devices must be designed, manufactured, and maintained in a manner that provides an adequate level of cybersecurity against unauthorized access attempts.

Subsection IX

Medical Devices and IVD Medical Devices with Diagnostic or Measurement Function

Article 54. Medical devices and IVD medical devices 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 on appropriate scientific and technical methods.

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

Paragraph 2. Values expressed numerically must use commonly accepted and standardized units of measurement whenever possible, and users of the medical device or IVD medical device must understand them.

Paragraph 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.

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

Paragraph 5. Operating instructions or indications of operating or adjustment parameters of a medical device or IVD medical device presented through a visual system must be understandable for the user and, as appropriate, for the patient.

Subsection X

Label and Instructions for Use

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

Paragraph 1. Each medical device and IVD medical device 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.

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

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

Subsection XI

Protection against Radiation

Article 56. Medical devices and IVD medical devices 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, restricting application to specified levels suitable for diagnostic and therapeutic purposes.

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

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

Article 59. Medical devices and IVD medical devices 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.

Sole 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.

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

Article 61. When medical devices and IVD medical devices are intended to emit hazardous or potentially hazardous radiation, which may reach the user, patient, or other person, they must be designed and manufactured in a way that ensures 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.

Sole paragraph. Such medical devices and IVD medical devices must be designed and manufactured in a way that ensures reproducibility of relevant variable parameters with an acceptable tolerance.

Subsection XII

Protection Against Risks Associated with Medical Devices and IVD Medical Devices Intended by the Manufacturer to Be Used by Lay People

Article 62. Medical devices and IVD medical devices intended to be used by lay people must be designed and manufactured in such a way that they perform adequately for the intended use or purpose, considering the skills and means available to lay users and the influence resulting from variations in the lay user's technique or the environment, which may be reasonably predictable.

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

Article 63. Medical devices and IVD medical devices intended to be used 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; and

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

Sole paragraph. When the risks associated with the interpretation of instructions for use cannot be reduced to acceptable levels, such risks may be mitigated by training.

Article 64. Medical devices and IVD medical devices intended to be used by lay people must, where appropriate, include means by which they:

I – can verify, at the time of use, whether the medical device or IVD medical device performs as intended by the manufacturer; and

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

Subsection XIII

Medical Devices and IVD Medical Devices Incorporating Material of Biological Origin

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

I – as appropriate, considering the species of animal, tissues and cells of animal origin, or their derivatives, they must come from animals that have been subjected to veterinary controls adapted to the intended use of the tissues; and

II – the obtainment, processing, preservation, analysis, and handling of tissues, cells, and substances of animal origin, or their derivatives, must be carried out in a way as to ensure the safety of patients, users and, as appropriate, of other people.

Sole 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 the use of such methods could cause unacceptable deterioration that would harm the medical device or IVD medical device.

Article 66. Regarding medical devices and IVD medical devices manufactured using biological substances other than those referred to in Article 69, the processing, conservation, analysis, and handling of such substances must be carried out in a manner that ensures the safety of patients, users and, as appropriate, other people, including those in the waste disposal chain.

Sole paragraph. Safety regarding viruses and other communicable 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 Medical Devices

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

Subsection I

Chemical, Physical, and Biological Properties

Article 68. Regarding 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, considering the intended purpose of the device and, when relevant, its absorption, distribution, metabolism, and excretion.

Article 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.

Article 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 such medicines and in such a way that the performance of medicines and devices is maintained according to their respective indications and intended use.

Article 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 intact skin.

Sole paragraph. Special attention should be paid to nanomaterials.

Subsection II

Protection against Radiation

Article 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.

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

Subsection III

Specific Requirements for Implantable Medical Devices

Article 74. Implantable medical devices must be designed and manufactured in a way that adequately eliminates or reduces risks associated with medical treatment.

Article 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 May Offer Patients or Users

Article 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 patients, users, and other people.

Article 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 hazard.

Sole paragraph. Devices must incorporate suitable means to reduce adequately 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

Article 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 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 Medical Devices

Article 79. The essential design and manufacturing principles referred to in this Section are complementary to the essential safety and performance principles referred to in Section II.

Subsection I

Chemical, Physical and Biological Properties

Article 80. Regarding the chemical, physical, and biological properties of IVD medical devices, 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 detected and measured must be considered in accordance with the intended purpose of the device.

Subsection II

Performance Characteristics

Article 81. IVD medical devices must achieve the analytical and clinical performance claimed by the manufacturer that is applicable to the intended use or purpose, considering the target patient population, intended users and use environment.

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

Paragraph 2. Analytical performance includes the following, 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; and

VI – sample stability.

Paragraph 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.

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

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

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

Article 84. The performance characteristics of the IVD medical device 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; and

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.

Paragraph 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.

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

CHAPTER III

FINAL AND TRANSITIONAL PROVISIONS

Article 85. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, in accordance with Law No. 6,437 of 20 August 1977, without prejudice to the applicable civil, administrative, and criminal liabilities.

Article 86. This Resolution revokes Collegiate Board Resolution – RDC no. 546 of 30 August 2021, published in the Federal Official Gazette no. 165 of 31 August 2021, Section 1, page. 131.

Article 87. Protocols of petitions for the regularization of medical devices and *in vitro* diagnosis (IVD)medical devices submitted before the period of validity of this Resolution shall be accepted with the essential safety and efficacy requirements defined in Collegiate Board Resolution – RDC no. 546 of 30 August 2021.

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

ANTONIO BARRA TORRES

Director President