COLLEGIATE BOARD RESOLUTION – RDC NO. 665 OF 30 MARCH 2022

Provides for the Good Manufacturing Practices for Medical Products and *In Vitro* Diagnostic Products.

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 Collegiate Board Resolution, as decided upon in Extraordinary Meeting – Rextra No. 6, held on 30 March 2022, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Article 1. This regulation provides for the Good Manufacturing Practices (GMP) for Medical Products and *In Vitro* Diagnostic Products, establishing the requirements that describe the GMP for methods and controls used in the design, purchasing, manufacturing, packaging, labeling, storage, distribution, installation, and technical assistance applicable to the manufacture of medical products and *in vitro* diagnostic products.

Paragraph 1. The requirements referred to in the caption of this article are intended to ensure that medical products and *in vitro* diagnostic products are safe and effective.

Paragraph 2. This Resolution incorporates into the national legal system the Resolution issued by the Mercosur's Common Market Group (GMC, in Portuguese) No. 20 of 17 November 2011, MERCOSUR/GMC/RES. No. 20/11, "Mercosur Technical Regulation on Good Manufacturing Practices for Medical Products and *In Vitro* Diagnostic Products (Revoking GMC Resolutions No. 04/95, 38/96, 65/96, and 131/96)".

Section II

Scope

Article 2. This regulation applies to manufacturers, distributors, storers, and importers of medical products and *in vitro* diagnostic products that are commercialized in Brazil.

Paragraph 1. When the manufacturers referred to in the caption of this article conclude that certain requirements established in this Resolution are not applicable to their processes, they must document the justification for such understanding.

Paragraph 2. The distributors of medical products and *in vitro* diagnostic products must comply with the following requirements of this Resolution, at least:

I – Chapters I, VII, and VIII, in full;

II – Chapter II, in full, except Section IV;

III – Chapter III, Section I;

IV – Chapter V, articles 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, and 77, in addition to Section IV; and

V – Chapter VI, in full, except Article 119.

Paragraph 3. The storers of medical products and *in vitro* diagnostic products must comply with the following requirements of this Resolution, at least:

I – Chapters I and VII, in full;

II – Chapter II, in full, except Section IV;

III – Chapter III, Section I;

IV – Chapter V, articles 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, and 77; and

V – Chapter VI, in full, except Article 119.

Paragraph 4. The importers of medical products and *in vitro* diagnostic products must comply with the following requirements of this Resolution, at least:

I – Chapters I, II, VII, VIII, and IX in full;

II – Chapter III, Section I and Section III;

III – Chapter IV, Article 63, items III, IV, and V;

IV – Chapter V, articles 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 85, 86, and 87, in addition to Sections III and IV; and

V – Chapter VI, in full, except Article 119.

Paragraph 5. Companies that carry out more than one activity must comply with the specific requirements defined for each activity.

Paragraph 6. The minimum requirements to be complied with, defined in Paragraphs 2, 3, and 4 of this Article, are applicable to distributors, storers, and importers, even if the provisions mention the word “manufacturer” only.

Section III

Definitions

Article 3. For the purposes of this Resolution, the following definitions are adopted:

I – technical assistance: maintenance or repair of a finished product, in order to restore it to its specifications;

II – quality audit: an established, systematic, and independent examination of a manufacturer's entire quality system, performed at regular intervals and with sufficient frequency to ensure that the quality system's activities and its results comply with the procedures specified in its quality system;

III – component: raw material, substance, part, piece, software, hardware, packaging, label, or instruction for use, used during the manufacture of a medical product or *in vitro* diagnostic product, intended to be included as part of the finished product;

IV – design input: description of physical attributes, indication of use, performance, compatibility, safety, efficacy, ergonomics, usability, information retrieved from previous designs, and risk management results, amongst other requirements for medical products or *in vitro* diagnostic products, that are used as the basis for a design development;

V – design output: results from the work at each stage of the design development process, including its final result, which, when concluded, is the basis for the device master record (DMR);

VI – damage: a person's physical lesion or health injury or a property or environmental deterioration;

VII – specifications: requirements that products, components, production activities, technical assistance, services, quality system, or any other activity must comply with;

VIII – to establish: to define, to document either in writing or electronically, and implement;

IX – manufacturer: any person who design, manufacture, assemble, or process a finished product, including those who execute sterilization, labeling, and packaging activities by contract;

X – executive management: a company's senior management team, responsible for providing resources and with authority to establish or modify the company's quality policy and system;

XI – risk management: policies, procedures, and management practices applied systematically to the tasks of analysis, assessment, control, and risk monitoring associated to a given product or process;

XII – lot or batch: quantity of a product elaborated in a manufacturing or sterilization cycle, the essential characteristic of which is homogeneity;

XIII – manufacturing material: material or substance used during the manufacturing process or to support this process, including cleaning agents, molding releasing agents, lubricating oils, sterilizing agents, or other subproducts from the manufacturing process;

XIV – non-conformity: failure to comply with a previously specified requirement;

XV – serial number or batch: unique combination of letters and/ or numbers, from which the complete purchase, manufacture, packaging, labeling, and distribution history of the finished products may be determined;

XVI – hazard: potential source of harm;

XVII – quality policy: totality of an organization's intentions and guidelines related to quality, expressed by the executive management;

XVIII – special process: any process the results of which cannot be fully verified by subsequent inspections and tests;

XIX – production: all activities involved in the manufacturing of a given product, from the receipt of components, through processing and packaging, until the obtention of the finished product;

XX – finished product: any product or accessory already packaged and labeled and ready for use;

XXI – quality: all the aspects and characteristics that allow a medical product or *in vitro* diagnostic product to meet suitability, safety, and performance requirements;

XXII – complaint: written, oral or electronic communication, related to non-acceptance of a product's identity, quality, durability, reliability, safety, efficacy, or performance;

XXIII – record: document set down in writing or electronically, which evidences data, facts, specific events, and the results achieved regarding compliance with the quality system procedures and standards;

XIV – device history record: compilation of records comprising the complete production history of a finished product;

XV – design history record: compilation of documents comprising the complete design history of a finished product;

XVI – device master record (DMR): compilation of documents including specifications, instructions, and procedures for the obtention of a finished product, in addition to its installation, technical assistance, and maintenance;

XVII – rework: partial or total manufacturing activities intended to correct non-conformities of a component, intermediary product, or finished product, so that it complies with the specifications defined in the DMR;

XVIII – design review: documented systematic and complete examination performed during the design development to assess its compliance to the design development planning and the objectives established;

XIX – risk: combination of occurrence probability and damage severity;

XXX – quality system: organizational structure, responsibilities, procedures, specifications, processes, and resources required for quality management;

XXXI – validation: proof by analysis and objective evidence that the requirements defined for a given purpose consistently lead to the expected result;

XXXII – verification: proof by analysis and presentation of objective evidence that the requirements specified have been met, including the process of assessing the results of an activity to determine compliance with the specifications established;

XXXIII – lifespan: manufacturer's estimated time length during which a product correctly performs its originally intended functions.

Paragraph 1. The procedures referred to in item II of the caption of this article must be implemented efficiently and also be adequate so the quality system's objectives can be achieved.

Paragraph 2. The quality audit referred to in item II of the caption of this article differs from other quality system's activities required in this Resolution.

Paragraph 3. When applied to a project, the validation mentioned in item XXXI of the caption of this article means establishing and documenting objective evidence that the product specifications meet the user's needs and its intended use.

Paragraph 4. When applied to a process, the validation referred to in item XXXI of the caption of this article means establishing and documenting objective evidence that the process will consistently produce a result that meets the predetermined specifications.

CHAPTER II

QUALITY SYSTEM GENERAL REQUIREMENTS

Section I

General requirements

Article 4. Each manufacturer must establish and maintain a quality system to ensure that the requirements of this Resolution are met and the products manufactured are safe, effective, and adequate for the intended use.

Sole paragraph. As part of quality system activities referred to in the caption of this article, each manufacturer must:

I – establish and maintain effective quality system instructions and procedures in accordance with the requirements in this Resolution; and

II – establish procedures to meet the legal provisions determined in the health legislation in force.

Section II

Management responsibility

Subsection I

Quality policy

Article 5. The executive management of each manufacturer must establish its quality policy and objectives, which must be measurable and consistent with the policy established.

Article 6. The executive management must keep the quality policy at all levels of the organization.

Article 7. The executive management must ensure that the quality policy is described in a quality manual and that this policy is understood by all employees who may affect or influence the quality of a product.

Subsection II

Organization and responsibilities

Article 8. Each manufacturer must:

I – establish and maintain an adequate organizational structure, expressed by an organizational chart, with sufficient personnel to ensure that the products are manufactured in accordance with the requirements in this Resolution;

II – establish the responsibility, authority, and interrelation of all personnel who manages, executes, and verifies quality-related work, with the required independence to carry out their duties; and

III – establish verification functions, provide adequate resources, and assign trained personnel to perform verification activities.

Article 9. Each manufacturer's executive management team must assign a person from the executive management team itself, who, regardless of other activities, has authority and responsibility to:

I – ensure that the quality system requirements are established and maintained in accordance with this Resolution;

II – report the quality system performance assessment to the executive management for review and provide information on the quality system improvement.

Sole paragraph. The assignment referred to in the caption of this article must be documented.

Subsection III

Management review

Article 10. The executive management of each manufacturer must assess the quality system adequacy and effectiveness at defined intervals and with sufficient frequency to ensure that the quality system meets the requirements in this Resolution and the objectives of the quality policy established.

Article 11. The management review must be conducted in accordance with the review procedures established and the results from each quality system review must be documented.

Article 12. Matters related to audit results, post-marketing information, process performance and product compliance, status of corrective and preventive actions, alterations that can affect the quality system or a product compliance, and regulatory requirements, amongst others, must be considered for management review.

Section III

Personnel

Article 13. Each manufacturer must have sufficient personnel with instruction, experience, training, and practice compatible with their job description, in order to ensure that all activities provided for in this Resolution are correctly performed.

Article 14. Descriptions must be kept defining authority, responsibility, and the necessary requirements of all personnel for the various tasks of the company.

Article 15. Each manufacturer must ensure that all personnel are trained to perform their assigned tasks properly.

Paragraph 1. The training referred to in the caption of this article must be conducted by qualified personnel, in accordance with the established procedures, to ensure that employees have an adequate understanding of their jobs and of the requirements in this Resolution that are applicable to their activities.

Paragraph 2. As part of the training mentioned in the caption of this article, all employees must be warned about product defects that may occur as a result of incorrect execution of their specific duties.

Paragraph 3. Personnel training must be documented.

Article 16. Each manufacturer must ensure that any external consultant that advises on methods or controls used for a product's design, purchase, manufacture, packaging, labeling, storage, installation, or technical assistance activities has sufficient qualifications – education, training, and experience – to advise on matters for which the consultant was hired.

Article 17. The consultant's hiring process must be conducted in accordance with the purchase control requirements determined in this Resolution.

Section IV

Risk management

Article 18. Each manufacturer must establish and maintain a continuous risk management process that covers the entire life cycle of a medical device or *in vitro* diagnostic product, from conception to discontinuation, in order to:

I – identify the associated hazards;

II – estimate and assess the risks involved;

III – control the associated risks; and

IV – assess the effectiveness of the controls established.

Article 19. The continuous risk management process must include the following elements:

I – analysis;

II – assessment;

III – control; and

IV – risk monitoring.

Article 20. The company's executive management team must designate the responsible professionals, establish the policy to determine the risk acceptability criteria, and also determine a periodic review of risk management activities, to ensure the adequacy and effectiveness of such activities.

Section V

Purchase controls

Article 21. Each manufacturer must establish and maintain procedures to ensure that components, manufacturing materials, and finished products manufactured, processed, labeled, or packaged by third parties, or stored by them under contract, comply with the specifications.

Sole paragraph. Each manufacturer must ensure that the services performed by third parties referred to in the caption of this article comply with the specifications established.

Article 22. Each manufacturer must establish and maintain, according to the impact on the quality of the finished product, criteria for the assessment of suppliers, specifying the requirements that must be complied with by suppliers, including quality requirements.

Article 23. Each manufacturer must assess and select potential suppliers, according to their ability to meet the previously established requirements, maintaining a record of approved suppliers.

Sole paragraph. The records of and results from supplier assessment must be kept.

Article 24. An agreement must be documented in which the suppliers agree to notify the manufacturer of any alteration in the product or service, so that the manufacturer can determine if the alteration affects the quality of the finished product.

Article 25. Each manufacturer must keep records of the purchase orders that clearly describe or refer to specifications, including quality requirements for components, manufacturing materials, finished products, or services requested or contracted.

Article 26. Each manufacturer must review and approve purchase orders prior to their release.

Article 27. Approval of purchase orders, including the date and the handwritten or digital signature of the person responsible for them, must be documented.

CHAPTER III

QUALITY DOCUMENTS AND RECORDS

Section I

General requirements

Article 28. Each manufacturer must establish and maintain document control procedures to ensure that all the documents referred to in this Resolution are correct and adequate for the

intended use and are understood by everyone who may affect or influence the quality of a product.

Article 29. Each manufacturer must designate personnel to assess and approve all documents established in this Resolution for adequacy before their issuance.

Sole paragraph. The approval referred to in the caption of this article, including the date and handwritten or digital signature of the person responsible for approving the documents, must be recorded.

Article 30. Each manufacturer must ensure that all documents are updated and available at the application points and that all unnecessary or obsolete documents are withdrawn from use or protected from unintended use.

Article 31. Alterations related to quality system specifications, methods, or procedures must be assessed, documented, reviewed, and approved by personnel whose job and level of responsibility are equivalent to those who performed the original review and approval.

Article 32. Each manufacturer must keep records of document alterations that must include:

I – description of the alteration;

II – identification of the altered documents;

III – identification of the affected documents;

IV – identification of the person responsible for the alteration;

V – date when the alteration was approved;

VI – date when the alteration becomes effective.

Article 33. A list of documents in force must be maintained to identify the documents' current status and ensure that only updated and approved documents are in use.

Article 34. All quality documents and records must be legible and stored in a way to minimize damage, prevents loss, and allow quick recovery.

Article 35. All digital documents and records must have backup copies.

Article 36. Documents and records considered confidential by the manufacturer may be signalized to alert the competent health authority.

Article 37. All necessary documents and records related to a product must be kept for a period of time equivalent to the product's lifespan, counting from the date of its distribution and in no situation this period can be shorter than two years.

Section II

Device history record

Article 38. Each manufacturer must keep device history records.

Article 39. Each manufacturer must establish and maintain procedures to ensure that the device history records are kept for each batch or series, in order to confirm that the products were

manufactured in accordance with the device master record and the requirements in this Resolution.

Article 40. The device history records must include or refer to the following information:

I – manufacturing date;

II – components used;

III – quantity manufactured;

IV – results from inspections and tests;

V – parameters of special processes;

VI – quantity released for distribution;

VII – labeling;

VIII – identification of serial number or production batch; and

IX – product final release.

Section III

Inspection and test records

Article 41. Each manufacturer must keep a record of the results from established inspections and tests, when these are directly related to product critical quality attributes.

Article 42. The records of established inspections and tests must include the acceptance criteria, results, equipment/ instrument used, and the date, and handwritten or digital signature of the person responsible for them.

CHAPTER IV

DESIGN CONTROL AND DEVICE MASTER RECORD (DMR)

Section I

Design control

Article 43. Each manufacturer must establish and maintain product design control procedures to ensure that the requirements specified for the design are complied with.

Article 44. Each manufacturer must establish and maintain plans that describe or refer to design and development activities, as well as the personnel responsible for each activity.

Paragraph 1. The plans referred to in the caption of this article must include any interaction between the various organizational and technical groups somehow involved in the design.

Paragraph 2. The plans referred to in the caption of this article must be assessed, updated, and approved during design development.

Article 45. Each manufacturer must establish and maintain procedures to ensure that product requirements are appropriate and meet its intended use, including user and patient needs, as well as the applicable legal and regulatory requirements.

Sole paragraph. The procedures referred to in the caption of this article must include a mechanism that allows incomplete, ambiguous, or conflicting requirements to be identified and addressed.

Article 46. Design input data must be documented, assessed, and approved by a qualified person assigned for such task.

Article 47. The approval of design requirements, including the date and handwritten or digital signature by the person responsible for it, must be documented.

Article 48. Each manufacturer must establish and maintain procedures for product design verification.

Paragraph 1. The design verification must be performed by a designated person and must ensure that the design output data match the design input data.

Paragraph 2. The design verification results, including the identification of the design verified, the verification methods, the date, and the name of the person in charge of the verification, must be documented in the design history record.

Article 49. Each manufacturer must define and document the design output data in a way that allows the assessment of the design's conformity to the requirements established as input data.

Paragraph 1. The design output data must meet the input data requirements, include the acceptance criteria, and identify the design characteristics that are essential for the product intended use.

Paragraph 2. The design output data must be documented, reviewed, and approved before its release.

Article 50. Each manufacturer must establish and maintain procedures to ensure that the assessment of design results are planned, conducted, and documented during the various stages of design development.

Sole paragraph. The procedures referred to in the caption of this article must ensure that representatives of all activities directly related to the design stage being reviewed are involved, as well as representatives from related areas and the specialists needed.

Article 51. The design review results must be documented in the design history record.

Article 52. Each manufacturer must establish and maintain procedures to ensure that product design is correctly translated into production specifications.

Article 53. Each manufacturer must establish and maintain a procedure to validate the product design.

Article 54. Design validation must be performed under predetermined operational conditions, during the initial manufacture of batches or units.

Article 55. Design validation must ensure that the product meets the user’s needs and the indication of use, and it must include trials of products under real or simulated use conditions.

Article 56. Design validation must include software validation, where appropriate.

Article 57. The project's validation results, including identification, methods, date, and handwritten or digital signature of those responsible, must be documented in the design history record.

Article 58. Whenever applicable, stability studies must be performed during design validation.

Article 59. Each manufacturer must ensure that the design is released for production only after approval by the personnel designated by the manufacturer for such task.

Paragraph 1. The designated personnel, referred to in the caption of this article, must review all records required for the design history record, in order to ensure that it is complete and the final design is compatible with the approved plans, before its release.

Paragraph 2. The release referred to in the caption of this article must be documented, including the date and the handwritten or digital signature of the person responsible for it.

Article 60. Each manufacturer must establish and maintain procedures for the identification, documentation, validation, review, and approval of design alterations prior to their implementation, including a risk assessment as within the risk management process.

Article 61. Each manufacturer must establish and maintain a design history record for each product.

Sole paragraph. The design history record must contain or refer to all records necessary to demonstrate that the design was developed in accordance with the design plan approved and the requirements in this Resolution.

Section II

Device Master Record (DMR)

Article 62. Each manufacturer must keep device master records (DMRs).

Article 63. The DMR for each type of product must include or refer to the following information:

I – product specifications, including the respective designs, composition, formulation, component specifications, software design specifications, and their source codes;

II – production process specifications, including infrastructure specifications, equipment, production methods and instructions, and environmental production specifications;

III – packaging and labeling specifications, including methods and processes used;

IV – inspection and testing procedures, with the respective acceptance criteria; and

V – Installation, maintenance, and technical assistance methods and procedures.

CHAPTER V

PROCESS AND PRODUCTION CONTROLS

Section I

General requirements

Article 64. Each manufacturer must design, conduct, control, and monitor all production processes to ensure that the manufactured product complies with its specifications.

Article 65. Each manufacturer must establish and maintain process control procedures that describe the process controls necessary to ensure compliance with product specifications.

Sole paragraph. Process controls must be established at any stage where deviation from product specifications may occur as a result of the manufacturing process.

Article 66. Process controls must include:

I – documented instructions, standard operational procedures, and methods that define and control the form of production, installation, and maintenance;

II – monitoring and control of process parameters;

III – compliance with technical regulations, standards, or reference codes; and

IV – instructions for approval of process start.

Article 67. The company's facilities must be properly designed in order to:

I – ensure the adequate flow of people;

II – allow the performance of all operations; and

III – prevent exchange or contamination of components, manufacturing materials, intermediate products, and finished products, and ensure the correct handling of such materials.

Article 68. Each manufacturer must provide suitable environmental conditions for production operations, in a way to prevent contamination or other adverse effects on the product.

Sole paragraph. For the purposes of the provisions in the caption of this article, the correct functioning of the environmental control systems established must be monitored, and the corresponding records must be kept.

Article 69. Each manufacturer must establish and maintain appropriate cleaning and sanitization procedures, as well as a schedule that meets the requirements in the manufacturing process specifications.

Sole paragraph. Each manufacturer must ensure that the personnel involved in cleaning activities understand the cleaning and sanitization procedures.

Article 70. Each manufacturer must ensure that personnel who are in contact with the product or its environment are clean, healthy, and dressed appropriately for the activity to be performed.

Article 71. Any person that, after clinical exam or supervisor observation, might be considered in a health condition that could affect the product, must be suspended from manufacturing operations until his or her health condition is considered adequate.

Sole paragraph. Personnel must be instructed to report to supervisors whenever they have a health condition that could affect the product.

Article 72. Each manufacturer must restrict food and beverage consumption to specific locations, so it does not affect production areas.

Article 73. Each manufacturer must establish and maintain procedures to prevent the contamination of equipment, components, manufacturing materials, intermediate products, and finished products with cleaning and disinfecting materials, including hazardous substances or contaminants generated by the manufacturing process.

Article 74. A pest control program must be established, and it must ensure that, whenever chemical agents are used, such agents do not affect the quality of the product.

Article 75. The treatment and disposal of waste, chemical effluents, and by-products must occur in accordance with the applicable legislation in force.

Article 76. Biological safety standards must be followed in cases where there is a biological risk.

Article 77. Each manufacturer must ensure compliance with the applicable standards related to workers' health, including the use of personal protective equipment compatible with the work processes performed.

Article 78. Each manufacturer must ensure that all equipment used in the manufacturing process is suitable for its intended use and correctly designed, built, and installed to facilitate maintenance, adjustment, cleaning, and use.

Article 79. Each manufacturer must establish and maintain a program for equipment maintenance, adjustment and, when necessary, cleaning, to ensure that all manufacturing specifications are complied with.

Sole paragraph. The maintenance program must be easily accessible to the personnel responsible for the equipment maintenance and operation.

Article 80. Maintenance activities must be recorded, with the date of performance and the identification of the personnel responsible for the task.

Article 81. Each manufacturer must ensure that any acceptable tolerances or inherent limitations are posted in a visible location or near the equipment requiring periodic adjustments, or readily available to the personnel responsible for such adjustments.

Article 82. Each manufacturer must establish and maintain procedures for the use and removal of manufacturing materials, to ensure that such materials are removed from the product or limited to a specified amount that does not adversely affect the product’s quality.

Article 83. Special processes must be conducted in accordance with established procedures and parameters to ensure compliance with the specifications.

Sole paragraph. The critical parameters of special processes must be monitored and recorded in the device history record.

Section II

Controls for packaging, labeling, and instructions for use

Article 84. Each manufacturer must establish procedures for packaging, in a way to protect the product from any alteration, damage, or contamination during the stages of processing, storage, handling, and distribution.

Article 85. Each manufacturer must establish and maintain procedures to ensure the integrity and prevent accidental mixing of labels, instructions for use, packaging materials, or identification tags.

Article 86. Each manufacturer must ensure that labels are designed, printed and, where applicable, applied so that they remain legible and adhered to the product during processing, storage, handling, and use.

Article 87. Labels and instructions for use must not be released for use until an authorized person has examined their compliance with the information they contain.

Paragraph 1. The approval of labels and instructions for use must be documented in the device history record, including the date, name and handwritten or digital signature of the person responsible for it.

Paragraph 2. In case of importers, the approval documentation referred to in Paragraph 1 of this article may be recorded in a specific document instead of the device history record.

Section III

Inspection and tests

Article 88. Each manufacturer must establish and maintain inspection and testing procedures, or other verification methods, to ensure product compliance with specified requirements throughout the manufacturing process.

Article 89. The conformity with the specified requirements must be assessed upon the receipt of components and manufacturing materials, as well as during intermediate stages of production and at the final approval of the finished product.

Paragraph 1. The results from the activities referred to in the caption of this article must be documented, including the conclusion – either approval or rejection.

Paragraph 2. The manufacturer must delegate the authority and responsibility for carrying out the activities referred to in the caption of this article.

Article 90. Components and manufacturing materials received, as well as components, intermediate products, and returned products, must not be used or processed until their compliance with the established requirements has been verified.

Article 91. Each manufacturer must establish and maintain procedures for the retention of components, manufacturing materials, intermediate products, and returned products, until inspections, tests, or other established verifications have been performed and documented.

Article 92. Finished products may only be released when the activities specified in the DMR have been completed and the associated documentation and data have been reviewed by a designated person to ensure that all acceptance criteria have been met.

Sole paragraph. The release of finished products must be documented, including the date and handwritten or digital signature of the person responsible for the task.

Section IV

Measurement and testing equipment

Article 93. Each manufacturer must ensure that all measurement and testing equipment, including mechanical, automated, or electronic equipment, is adequate for its intended purpose and capable of producing valid results.

Article 94. Each manufacturer must establish and maintain procedures to ensure that measurement and testing equipment is routinely calibrated, inspected, and controlled.

Article 95. Each manufacturer must establish and maintain calibration procedures that include specific guidelines and precision and accuracy limits, as well as instructions for corrective actions when the precision and accuracy limits are not achieved.

Article 96. Calibration must be carried out by personnel who have the necessary education, training, practice, and experience.

Article 97. Measurement and testing equipment must be identified to allow the calibration status to be determined.

Article 98. Each manufacturer must establish and maintain calibration standards for measurement equipment that are traceable to official national or international standards.

Sole paragraph. The manufacturer must establish and maintain its own calibration standard when there is no applicable calibration standard available.

Article 99. Each manufacturer must ensure that records are kept including calibration dates, the measurements obtained, name of the person responsible for the task, and the date scheduled for the next calibration.

Paragraph 1. The manufacturer must keep the records referred to in the caption of this article.

Paragraph 2. The records referred to in the caption of this article must be available to the personnel that uses the equipment and to those responsible for its calibration.

Article 100. Each manufacturer must establish and maintain procedures to ensure that handling, preservation, and storage of test, inspection, and measurement equipment are carried out in a manner that preserves its accuracy and adequacy for use.

Article 101. Each manufacturer must protect facilities and inspection, test, and measurement equipment, including testing hardware and software, from adjustments that could invalidate calibration.

Article 102. Each manufacturer must establish procedures to assess the impact of results from previous measurements, when non-conformities are found in measurement and testing equipment, and the result of such assessment must be documented.

Section V

Validation

Article 103. Special processes must be validated according to protocols previously established and the validation results, including the date and identification of the person responsible for its approval, must be recorded.

Article 104. Analytical methods, auxiliary systems to support the manufacturing process or environmental control, automated computerized systems, and software that may adversely affect product quality or the quality system must be validated.

Article 105. Each manufacturer must establish procedures to verify periodically its processes, analytical methods, auxiliary systems to support the manufacturing process or environmental control, automated computerized systems, and validated software and, when applicable, establish the frequency for revalidation.

Article 106. Each manufacturer must establish a procedure to control alterations in auxiliary systems, software, equipment, processes, methods, or other alterations that may influence the quality of products, including a risk assessment within the risk management process.

Paragraph 1. The procedure referred to in the caption of this article must describe the actions to be taken, including, when applicable, the need for requalification or revalidation.

Paragraph 2. The alterations mentioned in the caption of this article must be formally requested, documented, and approved before implementation.

CHAPTER VI

HANDLING, STORAGE, DISTRIBUTION, AND TRACEABILITY

Section I

Handling

Article 107. Each manufacturer must establish and maintain procedures to ensure that inversions (exchanges), damage, deterioration, or other adverse effects that affect components, manufacturing materials, intermediate products, finished products, and quality control samples do not occur during any stage of handling.

Article 108. Each manufacturer must establish and maintain procedures to identify the conformity of components, manufacturing materials, intermediate products, and finished products to ensure that only those duly approved are used or distributed.

Article 109. The procedures referred to in Article 107 and Article 108 of this Resolution must ensure that components, manufacturing materials, intermediate products, or finished products:

I – are not used or distributed, when their quality or the “fit for use” status has been lost over time;

II – closest to the expiration date are distributed or used first; and

III – are not distributed or used when expired.

Section II

Storage and distribution

Article 110. Each manufacturer must establish and maintain procedures to identify components, manufacturing materials, intermediate products, finished products, and quality control samples, in a way to prevent inversions (exchanges) during storage.

Article 111. Components, manufacturing materials, intermediate products, finished products, and quality control samples must be stored in physical and environmental conditions that prevent damage, deterioration, or other adverse effects during the period in which they remain in storage.

Article 112. Each manufacturer must keep distribution records that include or refer to:

I – the consignee's name and address;

II – the identification and quantity of products shipped, with the shipment date; and

III – any numerical control used for traceability.

Section III

Identification, traceability, and non-conformities

Article 113. Each manufacturer must establish and maintain procedures to identify components, manufacturing materials, intermediate products, and finished products during all stages of storage, production, distribution, and installation, in order to avoid confusion and to ensure the correct fulfillment of orders.

Article 114. Each manufacturer must identify each product unit, lot, or batch with a serial or batch number, and such identification must be included in the device history record.

Sole paragraph. In case of distributors, storers, and importers, the identification referred to in the caption of this article may be recorded in a specific document instead of the device history record.

Article 115. Each manufacturer must establish and maintain procedures to ensure that components, manufacturing materials, intermediate products, finished products, and returned products, which are not in conformity with the established requirements, are not used or installed inadvertently.

Sole paragraph. The procedures referred to in the caption of this article must contain instructions for the identification, documentation, assessment, segregation, and disposal of non-conforming components, manufacturing materials, intermediate products, and finished products.

Article 116. The assessment of non-conforming components, manufacturing materials, intermediate products, and finished products must include the need for investigation and notification of the people and/ or organizations involved in the non-conformity.

Sole paragraph. The assessment results and eventual investigations referred to in the caption of this article must be recorded.

Article 117. Responsibility for review and authority to dispose of non-conforming components, manufacturing materials, intermediate products, finished products, and returned products must be defined.

Article 118. The review and disposal process for non-conforming components, manufacturing materials, intermediate products, finished products, and returned products must be described in an established procedure.

Paragraph 1. The disposal of the products referred to in the caption of this article must be documented, and a record of the decision rationale and a handwritten or digital signature of the person or people responsible for the disposal must be kept.

Paragraph 2. In case of authorization to use the products referred to in the caption of this article, the decision must be based on a technically justifiable risk assessment.

Article 119. Each manufacturer must establish and maintain procedures for the rework, re-inspection, and reassessment of intermediate or finished products after rework, in order to ensure the products meet their original specifications.

Sole paragraph. Activities related to rework and reassessment of products referred to in the caption of this article, including issues related to rework activities, must be documented in the device history record.

CHAPTER VII

CORRECTIVE AND PREVENTIVE ACTIONS

Section I

General requirements

Article 120. Each manufacturer must establish and maintain procedures to:

I – analyze processes, work operations, quality audit reports, quality records, technical assistance records, complaints, returned products, and other quality data sources, in order to identify existing and potential causes for non-conformities related to a product, process, or quality system;

II – investigate the cause for non-conformities related to a product, process, or quality system;

III – identify and execute the necessary actions to prevent the occurrence, correct the problem, and prevent the recurrence of non-conformities;

IV – verify or validate the corrective action effectiveness and ensure that such corrective action does not adversely affect the product;

V – record the activities related to corrective and preventive actions;

VI – ensure that information about quality problems or non-conforming products is properly disseminated amongst those directly involved in maintaining product quality or preventing the occurrence of such problems;

VII – submit relevant information about quality issues identified, as well as preventive and corrective actions to the executive management for awareness and follow-up, and also to the competent health authority, when applicable; and

VIII – determine recall of products and other field actions that are relevant in case of products already distributed.

Paragraph 1. The analysis referred to in item I of this article must be based on a valid statistical technique to detect recurring quality problems, when applicable.

Paragraph 2. In order to comply with the provisions in item IV of this article, any alteration made must follow the alteration control procedures and validation protocols established, when applicable.

Section II

Management of complaints

Article 121. Each manufacturer must establish and maintain procedures to receive, examine, assess, investigate, and file complaints, ensuring that:

I – complaints are received, documented, examined, assessed, investigated, and filed by a formally designated unit;

II – complaints are notified to the competent health authority, when applicable;

III – complaints are examined to verify the need for an investigation;

IV – all complaints involving a possible non-conformity of a product are examined, assessed, and investigated;

V – when an investigation is conducted, records are kept, including the following information:

a) name of the product;

b) date the complaint was received;

c) any control number used;

d) complainant's name, address, and telephone number;

e) nature of the complaint; and

f) investigation date and results, including actions taken.

Paragraph 1. When the investigation referred to in item III of this article is not conducted, the unit must record the reason why the investigation was not carried out and the names of the people responsible for the decision not to investigate.

Paragraph 2. When any complaint referred to in item IV of this article is related to death, injury, or threat to public health, it must be immediately examined, assessed, and investigated.

Section III

Quality audit

Article 122. Each manufacturer must conduct and document quality audits to assess the quality system's compliance with the requirements established.

Article 123. Quality audits must be carried out by trained personnel, in accordance with the audit procedures established, and who have no direct responsibility for the matters being audited.

Sole paragraph. Those responsible for conducting the quality audit cannot have direct responsibility for the matters being audited.

Article 124. Those responsible for the audited areas must be notified about non-conformities identified.

CHAPTER VIII

INSTALLATION AND TECHNICAL ASSISTANCE

Article 125. Each manufacturer must establish and maintain adequate instructions and procedures for the correct installation of products.

Article 126. During the product installation, either by the manufacturer or its authorized representative, there must be a verification whether the product’s operation meets the criteria established.

Sole paragraph. The results from the verification referred to in the caption of this article must be recorded.

Article 127. Each manufacturer must ensure that installation instructions and procedures are distributed with the product or are otherwise available to the person responsible for the product installation.

Article 128. Each manufacturer must establish and maintain procedures to ensure that finished products submitted to technical assistance by the manufacturer or his representative meet the specifications.

Article 129. Each manufacturer must establish and maintain procedures to ensure that technical assistance records are maintained and include the following information:

I – the product submitted to technical assistance;

II – the control number used;

III – the technical assistance date;

IV – the technical assistance provider´s identification;

V – the description of the service performed; and

VI – the results from inspections and tests to approve the service.

Article 130. Each manufacturer must assess the technical assistance records periodically.

Sole paragraph. In the cases where the assessment referred to in the caption of this article identifies failure trends, which represent danger, or records involving death or serious injury, a corrective/ preventive action must be initiated in accordance with the requirements in this Resolution.

CHAPTER IX

STATISTICAL TECHNIQUES

Article 131. Each manufacturer must establish and maintain procedures to identify valid statistical techniques to verify the quality system performance and the process ability to meet the specifications established.

Article 132. Sampling plans must be recorded in written and based on valid statistical logics.

Article 133. Each manufacturer must establish and maintain procedures to ensure that sampling methods are adequate for their intended use and that they are regularly reviewed.

Article 134. The review of sampling plans must consider the occurrence of product non-conformities, quality audit reports, complaints, and other indicators.

CHAPTER X

FINAL PROVISIONS

Article 135. The documentation that proves compliance with the requirements established in this Resolution must be available whenever requested by health surveillance authorities.

Article 136. Failure to comply with the provisions contained in this Resolution shall be considered an infraction of health regulations, pursuant to Law No. 6,437 of 20 August 1977 and its updates, without prejudice to the applicable civil, administrative, and criminal liabilities.

Article 137. The following regulations are hereby revoked:

I – Collegiate Board Resolution – RDC No. 16 of 28 March 2013, published in the Federal Official Gazette No. 61 of 1 April 2013, Section 1, page 75; and

II – Normative Instruction – IN No. 8 of 26 December 2013, published in the Federal Official Gazette No. 252 of 30 December 2013, Section 1, page 758.

Article 138. This Resolution enters into force on 2 May 2022.

ANTONIO BARRA TORRES

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