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Body: Ministry of Health/National Health Surveillance Agency/Collegiate Board of Directors

RDC RESOLUTION No. 665, OF MARCH 30, 2022

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

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the powers conferred upon it by art. 15, III and IV, allied to art. 7, III and IV, of Law No. 9.782, of January 26, 1999, and art. 187, VI, paragraph 1 of the Internal Regulations approved by Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, hereby decides to adopt the following Resolution, as resolved at a meeting held on March 30, 2022, and I, the Chief Executive Officer, hereby determine its publication.

CHAPTER I INITIAL PROVISIONS

Section I Purpose

Art. 1 This Resolution provides on 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, manufacture, packaging, labeling, storage, distribution, installation and technical assistance applicable to the manufacture of medical products and in vitro diagnostic products.

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

§ 2 This Resolution incorporates, into the national legal system, the MERCOSUR Common Market Group (GMC) Resolution No. 20, of November 17, 2011, MERCOSUR/GMC/RES. No. 20/11, "MERCOSUR Technical Regulation on Good Manufacturing Practices for Medical Products and In Vitro Diagnostic Products (Revocation of GMC Res. No. 04/95, 38/96, 65/96 and 131/96)".

Section II Scope

Art. 2 This Resolution applies to manufacturers, distributors, storages and importers of medical products and in vitro diagnostic products that are marketed in Brazil.

§ 1 When the manufacturers referred to in the caput of this article conclude that certain requirements established in this Resolution are not applicable to their processes, they shall document the rationale for such understanding.

§ 2 Distributors of medical products and in vitro diagnostic products shall comply, at least, with the following requirements of this Resolution:

I - Chapters I, VII and VIII, in their entirety;

II - Chapter II, in its entirety, 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 its entirety, except art. 119.

§ 3 Storages of medical products and in vitro diagnostic products shall comply, at least, with the following requirements of this Resolution:

I - Chapters I and VII, in their entirety;

II - Chapter II, in its entirety, 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 its entirety, except art. 119.

§ 4 Importers of medical products and in vitro diagnostic products shall comply, at least, with the following requirements of this Resolution:

I - Chapters I, II, VII, VIII and IX in their entirety;

II - Chapter III, Section I and Section III;

III - Chapter IV, art. 63, clauses 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 its entirety, except art. 119.

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

§ 6 The minimum requirements to be complied with, defined in §§ 2, 3 and 4 of this article, are applicable to distributors, storages and importers, even if the provision only mentions the word manufacturer.

Section III Definitions

Art. 3 For the purpose of this Resolution, the following definitions are adopted:

I - technical assistance: maintenance or repair of a finished product in order to return it to its specifications;

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

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

IV - design input data: a description of the physical attributes, indication of use, performance, compatibility, safety, effectiveness, ergonomics, usability, information from previous designs, and risk management results, among other requirements of a medical product or in vitro diagnostic product that are used as the basis of their design;

V - design output data: result of the work in each phase of the design and its final result which, when finished, is the basis for the product master record (PMR);

VI - harm: physical injury or damage to a person's health, or damage to property or the environment;

VII - specifications: requirements to which products, components, production activities, technical assistance, services, quality system or any other activity shall conform with; VIII - establish: define,

document in written or electronic form, and implement;

IX - manufacturer: any person who designs, manufactures, assembles, or processes a finished product, including those who perform contracted functions of sterilization, labeling, and packaging;

X - executive management: senior management of the company, responsible for providing resources and with the authority to establish or change the company's policy and quality system;

XI - risk management: the systematic application of policies, procedures, and management practices to the tasks of analyzing, assessing, controlling, and monitoring risks associated with a given product or process;

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

XIII - manufacturing material: material or substance employed in the manufacturing process or in order to facilitate this process, including cleaning agents, mold release agents, lubricating oils, sterilants, or other by-products of the manufacturing process;

XIV - non-conformity: failure to meet a previously specified requirement;

XV - serial or batch number: a distinct combination of letters or numbers, or both, from which the complete history of purchasing, manufacturing, packaging, labeling, and distribution of finished products can be determined;

XVI - danger: potential source of harm;

XVII - quality policy: the totality of an organization's intentions and guidelines with regard to quality, as expressed by the executive management;

XVIII - special process: any process whose results cannot be completely verified by subsequent inspections and tests;

XIX - production: all the operations involved in manufacturing a given product, from the receipt of the components, through processing and packaging, to obtaining the finished product;

XX - finished product: any product or accessory suitable for use, packaged and labeled;

XXI - quality: the totality of aspects and characteristics that enable a medical product or in vitro diagnostic product to meet the requirements on being suitable for use, including safety and performance;

XXII - complaint: written, oral or electronic communication with regard to the non-acceptance of the identity, quality, durability, reliability, safety, effectiveness or performance of a product;

XXIII - record: physical or electronic document that evidences data, facts, specific events, and results achieved in relation to conformity with quality system procedures and standards;

XIV - product history file: compilation of records containing the complete production history of a finished product;

XV - design history file: compilation of documents containing the complete history of the design of a finished product;

XVI - product master record (PMR): compilation of documents containing specifications, instructions, and procedures for obtaining a finished product, as well as for its installation, technical assistance, and maintenance;

XVII - rework: part or the totality of the manufacturing operation intended to correct non-conformity of a component, intermediate or finished product, so that it meets the specifications defined in the DMR;

XVIII - design review: a documented, systematic, and thorough examination performed during the course of the development of the design to assess its suitability to the established plan and objectives;

XIX - risk: combination between probability of occurrence and severity of harm;

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

XXXI - validation: confirmation by analysis and objective evidence that the requirements defined for a certain purpose consistently lead to the expected result;

XXXII - verification: confirmation, by analysis and presentation of objective evidence, that specified requirements have been met, including the process of examining the results of an activity to determine conformity with established specifications; and

XXXIII - shelf life: period of time estimated by the manufacturer in which a product correctly fulfills the functions for which it was designed.

§ 1 The procedures referred to in item II of the caput of this article shall be implemented in an efficient and suitable manner to achieve the objectives of the quality system.

§ 2 The quality audit referred to in item II of the caput of this article differs from other quality system activities required by this Resolution.

§ 3 Regarding a project, the validation referred to in item XXXI of the caput of this article means establishing and documenting objective evidence that the product specifications meet the user's needs and its intended use.

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

CHAPTER II

GENERAL REQUIREMENTS OF THE QUALITY SYSTEM

Section I General

Requirements

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

Sole paragraph. As part of its activities in the quality system mentioned in the caput of this article, each manufacturer shall:

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

II - establish procedures to meet the legal provisions provided for in the health legislation in force.

Section II

Management responsibility

Subsection I

Quality Policy

Art. 5 The executive management of each manufacturer shall establish its policy and objectives on commitment to quality, which shall be measurable and consistent with the established policy.

Art. 6 The executive management shall maintain the quality policy at all levels of the organization.

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

Subsection II

Organization and responsibilities

Art. 8 Each manufacturer shall:

I - establish and maintain an appropriate organizational structure, represented by an organizational chart, with personnel sufficient to ensure that products are manufactured in accordance with the requirements of this Resolution;

II - establish the responsibility, authority, and interrelation of all personnel who manage, perform, and verify quality-related work, with the independence necessary in the exercise of their responsibilities; and

III - establish verification functions, provide suitable resources, and assign trained personnel to perform the verification activities.

Art. 9 The executive management of each manufacturer shall appoint an individual from the executive management itself who, regardless of other functionss, has the authority and responsibility to:

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

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

Sole paragraph. The appointment referred to in the caput of this article shall be documented.

Subsection III

Management review

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

Art. 11. The management review shall be performed in accordance with established review procedures and the results of each quality system review shall be documented.

Art. 12. Matters related to audit results, post-marketing information, process performance and product conformity, status of corrective and preventive actions, changes that may affect the quality system or product conformity, regulatory requirements, among others, shall be taken into consideration for management review.

Section III Personnel

Art. 13. Each manufacturer shall have sufficient personnel with education, experience, training and practice compatible with the duties of the position, in order to ensure that all activities provided for in this Resolution are correctly performed.

Art. 14. Descriptions defining authority, responsibility and necessary requirements of all personnel for the various tasks of the company shall be maintained.

Art. 15. Each manufacturer shall ensure that all personnel are trained to properly perform the tasks assigned to them.

§ 1 The training mentioned in the caput of this article shall be conducted in accordance with the procedures established by qualified persons to ensure that employees have an adequate understanding of their regular functions and of the requirements of this Resolution applicable to their functions.

§ 2 As part of the training referred to in the caput of this article, all employees shall be warned of product defects that may occur as a result of incorrect performance of their specific functions.

§ 3 The training of the personnel shall be documented.

Art. 16. Each manufacturer shall ensure that any consultant who advises on methods employed or controls used for the design, purchase, manufacture, packaging, labeling, storage, installation or technical assistance of products, has sufficient qualifications - education, training and experience - to advise on the matters for which they were hired.

Art. 17. The hiring of consultants shall be performed in accordance with the purchasing control requirements set forth in this Resolution.

Section IV

Risk management

Art. 18. Each manufacturer shall establish and maintain an ongoing risk management process that involves the entire life cycle of a medical product or in vitro diagnostic product, from its conception to discontinuation, to:

I - identify the associated hazards;

II - estimate and evaluate the risks involved;

III - control the associated risks; and

IV - assess the effectiveness of the established controls.

Art. 19. The ongoing risk management process shall include the following elements: I - analysis;

II - assessment;

III - control; and

IV - risk monitoring.

Art. 20. The company's executive management shall appoint the professionals responsible, establish the policy for determining the criteria for risk acceptability, as well as determine a periodic review of risk management activities, in order to ensure the adequacy and effectiveness of these activities.

Section V

Purchasing controls

Art. 21. Each manufacturer shall 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, are in conformity with the specifications.

Sole paragraph. Each manufacturer shall ensure that the services performed by third parties mentioned in the caput of this article are in conformity with the specifications established by it.

Art. 22. Each manufacturer shall establish and maintain, according to the impact on the quality of the final product, criteria for assessing suppliers, specifying the requirements, including quality requirements, which shall be met by suppliers.

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

Sole paragraph. Records of supplier assessment and results shall be maintained.

Art. 24. An agreement, in which the suppliers undertake to notify the manufacturer of any change to the product or service, so that the manufacturer can determine whether the change affects the quality of the finished product, shall be documented.

Art. 25. Each manufacturer shall maintain records of purchase orders that clearly describe or reference specifications, including quality requirements, for components, manufacturing materials, finished products, or services ordered or hired.

Art. 26. Each manufacturer shall review and approve the purchasing documents prior to their release.

Art. 27. Approval of purchase orders, including the date and manual or electronic signature of the person responsible, shall be documented.

CHAPTER III

DOCUMENTS AND QUALITY RECORDS

Section I General Requirements

Art. 28. Each manufacturer shall establish and maintain document control procedures to ensure that all documents indicated in this Resolution are correct and suitable for their intended use, and that they are understood by all who may affect or influence the quality of a product.

Art. 29. Each manufacturer shall appoint people to assess and approve all documents established in this Resolution for adequacy prior to their issuance.

Sole paragraph. The approval referred to in the caput of this article, including the date and manual or electronic signature of the person responsible for approving the documents, shall be documented.

Art. 30. Each manufacturer shall ensure that all documents are up to date and available at application sites, and that all unnecessary or obsolete documents are withdrawn from use, or protected from unintended use.

Art. 31. Changes to specifications, methods, or procedures relating to the quality system shall be assessed, documented, reviewed, and approved by persons whose function and level of responsibility are equivalent to those who performed the original review and approval.

Art. 32. Each manufacturer shall maintain records of changes in documents that shall include:

I - description of the change;

II - identification of the documents changed;

III - identification of the documents affected;

IV - identification of the person responsible for the change;

V - date of approval of the change; and

VI - the date on which the change becomes effective.

Art. 33. A list of current documents shall be maintained to identify the current situation of the documents and ensure that only current and approved documents are in use.

Art. 34. All quality documents and records shall be legible and maintained as to minimize damage, prevent losses, and enable their quick retrieval.

Art. 35. All digitally archived documents and records shall be backed up.

Art. 36. Documents and records deemed confidential by the manufacturer may be flagged to alert the competent health authority.

Art. 37. All necessary documents and records relating to a product shall be maintained for a period of time equivalent to the shelf life of the product, counted from the date of its distribution, and in no case less than two years.

Section II

Product History File

Art. 38. Each manufacturer shall maintain product history files.

Art. 39. Each manufacturer shall establish and maintain procedures to ensure that the product history files are maintained for each batch or series to demonstrate that products have been manufactured in accordance with the product master record and the requirements of this Resolution.

Art. 40. The product history file shall include, or reference, the following information:

I - manufacture date;

II - components used;

III - quantity manufactured;

IV - inspection and test results;

V - special process parameters;

VI - quantity released for distribution;

VII - labeling;

VIII - identification of serial number or production batch; and

IX - final product release.

Section III

Records of inspections and tests

Art. 41. Each manufacturer shall maintain records of the results of inspections and tests established, when these are directly related to critical quality attributes of the product.

Art. 42. The records of the inspections and tests established shall include the acceptance criteria, the results, the equipment/instrument used, and the date and manual or electronic signature of the person responsible.

CHAPTER IV

DESIGN CONTROL AND PRODUCT MASTER RECORD (PMR)

Section I

Project Control

Art. 43. Each manufacturer shall establish and maintain product design control procedures to ensure that the specified design requirements are met.

Art. 44. Each manufacturer shall establish and maintain plans that describe or reference design and development activities, as well as the persons responsible for each activity.

§ 1 The plans referred to in the caput of this article shall include any interaction between the various organizational and technical groups that have some interface with the design.

§ 2 The plans referred to in the caput of this article shall be assessed, updated, and approved as the development of the design progresses.

Art. 45. Each manufacturer shall establish and maintain procedures to ensure that the requirements related to a product are appropriate and meet its intended use, including user and patient needs, and applicable legal and regulatory requirements.

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

Art. 46. Design input data shall be documented, assessed, and approved by a qualified appointed person.

Art. 47. Approval of design requirements, including the date and the manual or electronic signature of the person responsible for the approval, shall be documented.

Art. 48. Each manufacturer shall establish and maintain procedures for product design verification.

§ 1 Design verification shall be performed by an appointed person and shall ensure that the design output data meets the input data.

§ 2 The results of the project verification, including the identification of the verified design, the verification methods, the date and the name of the person responsible for the verification, shall be documented in the design history file.

Art. 49. Each manufacturer shall define and document the design output data as to allow the assessment of the design's conformity with the requirements established as input data.

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

§ 2 The design output data shall be documented, reviewed, and approved prior to its release.

Art. 50. Each manufacturer shall establish and maintain procedures to ensure that assessments of design results are planned, conducted, and documented at the various stages of design development.

Sole paragraph. The procedures referred to in the caput of this article shall ensure that representatives of all functions directly related to the stage of the design being reviewed, as well as individuals from related areas, and the necessary specialists, are involved.

Art. 51. The results of the design review shall be documented in the design history file.

Art. 52. Each manufacturer shall establish and maintain procedures to ensure that the product design is correctly translated into production specifications.

Art. 53. Each manufacturer shall establish and maintain a procedure to validate the product design.

Art. 54. Design validation shall be performed under predetermined operating conditions, in the initial batch or unit production.

Art. 55. Design validation shall ensure that the product meets the user's needs and indication of use, and shall include product testing under real or simulated conditions of use.

Art. 56. Design validation shall include software validation, where appropriate.

Art. 57. The results of the design validation, including identification, methods, date and manual or electronic signature of those responsible, shall be documented in the design history file.

Art. 58. In design validation, stability studies shall be performed whenever applicable.

Art. 59. Each manufacturer shall ensure that the design is released for production only when it is approved by the persons appointed by the manufacturer.

§ 1 The appointed persons, mentioned in the caput of this article, shall review all records required for the design history file, in order to ensure that it is complete and that the final design is compatible with the approved plans, prior to its release.

§ 2 The release referred to in the caput of this article shall be documented, including the date and manual or electronic signature of the person responsible.

Art. 60. Each manufacturer shall establish and maintain procedures for identifying, documenting, validating, reviewing and approving design changes prior to their implementation, including a risk assessment within the risk management process.

Art. 61. Each manufacturer shall establish and maintain a design history file for each product.

Sole paragraph. The design history file shall contain or reference all records necessary to demonstrate that the project was developed in accordance with the approved design plan and the requirements of this Resolution.

Section II

Product Master Record (PMR)

Art. 62. Each manufacturer shall maintain product master records (PMRs).

Art. 63. The PMR for each product type shall include or reference the following information:

I - product specifications, including their respective drawings, composition, formulation, component specifications, software design specifications and their source codes;

II - specifications of the production process, including specifications of infrastructure, equipment, production methods and instructions, and production environmental specifications;

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

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

V - methods and procedures for installation, maintenance, and technical assistance.

CHAPTER V

PROCESS AND PRODUCTION CONTROLS

Section I General Requirements

Art. 64. Each manufacturer shall design, conduct, control, and monitor all production processes in order to ensure that the product is in conformity with its specifications.

Art. 65. Each manufacturer shall establish and maintain process control procedures that describe the process controls necessary to ensure conformity with product specifications.

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

Art. 66. Process controls shall include:

I - documented instructions, standard operating procedures, and methods that define and control the manner of production, installation, and maintenance;

II - monitoring and control of process parameters;

III - conformity with technical rules, standards, or reference codes; and IV -

instructions for process start release.

Art. 67. The company's facilities shall be properly designed to: I - ensure adequate

flow of people;

II - provide for the performance of all operations; and

III - prevent mix-ups or contamination of components, manufacturing materials, intermediate and finished products, and ensure the proper handling of these materials.

Art. 68. Each manufacturer shall provide suitable environmental conditions for production operations in order to prevent contamination or other adverse effects on the product.

Sole paragraph. For the purposes of the provisions in the caput of this article, the correct functioning of the established environmental control systems shall be monitored, and the corresponding records shall be maintained.

Art. 69. Each manufacturer shall establish and maintain adequate cleaning and sanitization procedures and a schedule that meets the requirements of the manufacturing process specifications.

Sole paragraph. Each manufacturer shall ensure that the personnel involved understand the cleaning and sanitization procedures.

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

Art. 71. Any person who, by medical examination or by observation of supervisors, appears to be in a health condition that could affect the product, shall be removed from operations until the health condition is deemed adequate.

Sole paragraph. Personnel shall be instructed to report to supervisors when they are in a health condition that could affect the product.

Art. 72. Each manufacturer shall limit the consumption of food and beverages to specific locations so as not to affect the production areas.

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

Art. 74. A pest control program shall be established, and it shall be ensured that whenever chemical agents are used, these agents do not affect the quality of the product.

Art. 75. The treatment and disposal of waste, chemical effluents, and byproducts shall occur according to the applicable legislation in force.

Art. 76. Biological safety standards shall be observed in cases where a biological hazard is present.

Art. 77. Each manufacturer shall ensure conformity with applicable standards related to workers' health, including the use of personal protective equipment, that are compatible with the work processes performed.

Art. 78. Each manufacturer shall ensure that all equipment used in the manufacturing process is suitable for its intended use and properly designed, constructed, and installed for ease of maintenance, adjustment, cleaning, and use.

Art. 79. Each manufacturer shall establish and maintain a program for maintenance, adjustments, and, when necessary, cleaning of the equipment to ensure that all manufacturing specifications are met.

Sole paragraph. The maintenance program shall be in a place easily accessible to the personnel in charge of maintenance and use of the equipment.

Art. 80. The maintenance activities shall be registered, with the date they took place and the identification of the people in charge.

Art. 81. Each manufacturer shall ensure that any acceptable tolerances or inherent limitations are posted in a visible location or near equipment that requires periodic adjustment, or are readily available to personnel in charge of such adjustments.

Art. 82. Each manufacturer shall establish and maintain procedures for the use and removal of manufacturing materials to ensure that these materials are removed from the product or limited to a specified amount that does not adversely affect the quality of the product.

Art. 83. Special processes shall be conducted according to established procedures and parameters to ensure conformity with specifications.

Sole paragraph. Critical parameters of special processes shall be monitored and recorded in the product history file.

Section II

Controls on packaging, labeling and instructions for use

Art. 84. Each manufacturer shall establish procedures for the packaging of products in order to protect the product from any alteration, damage, or contamination during the processing, storage, handling, and distribution stages.

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

Art. 86. Each manufacturer shall 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.

Art. 87. Labels and instructions for use shall not be released for use until an authorized person has examined that they are in conformity with the information contained therein.

§ 1 Approval of labels and instructions for use shall be documented in the product history file, including date, name, and manual or electronic signature of the person responsible.

§ 2 In the case of importers, the documentation of the approval referred to in § 1 of this article can be registered in a document of its own instead of the product history file.

Section III Inspection and Testing

Art. 88. Each manufacturer shall establish and maintain procedures for inspection, tests, or other means of verification to ensure conformity with specified requirements throughout the manufacturing chain.

Art. 89. Conformity with specified requirements shall be assessed on the receipt of components and manufacturing materials, as well as at intermediate stages of production and upon final acceptance of the finished product.

§ 1 The results of the activities referred to in the caput of this article shall be documented, including their conclusion - acceptance or rejection.

§ 2 The authority and responsibility for performing the activities referred to in the caput of this article shall be defined by the manufacturer.

Art. 90. Components and manufacturing materials received, as well as components, intermediate products and returned products, shall not be used or processed until they their conformity with the established requirements have been verified.

Art. 91. Each manufacturer shall establish and maintain procedures for retaining components, manufacturing materials, intermediate products, and returned products until inspections, tests, or other established verifications have been performed and documented.

Art. 92. Finished products can only be released when the activities specified in the PMR have been completed and the associated documentation and data have been reviewed, by aan appointed person, to ensure that all acceptance criteria have been met.

Sole paragraph. The release of finished products shall be documented, including the date and manual or electronic signature of the person responsible.

Section IV

Test and measurement equipment

Art. 93. Each manufacturer shall ensure that all test and measurement equipment, including mechanical, automated, or electronic equipment, is suitable for its intended purpose and capable of producing valid results.

Art. 94. Each manufacturer shall establish and maintain procedures to ensure that the test and measurement equipment is routinely calibrated, inspected, and controlled.

Art. 95. Each manufacturer shall establish and maintain calibration procedures that include specific guidelines and limits for accuracy and precision, as well as prescriptions for corrective action when the limits for accuracy and precision are not met.

Art. 96. Calibration shall be performed by personnel with the necessary education, training, practice, and experience.

Art. 97. Test and measurement equipment shall be identified as to provide for determining the calibration status.

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

Sole paragraph. When no applicable calibration standard is available, the manufacturer shall establish and maintain its own standard.

Art. 99. Each manufacturer shall ensure the maintenance of records of the dates of calibration, measurements obtained, person in charge of such task, and the next date for this operation.

§ 1 The records mentioned in the caput of this article shall be maintained by the manufacturer.

§ 2 The records mentioned in the caput of this article shall be available to the personnel using the equipment and to those responsible for its calibration.

Art. 100. Each manufacturer shall establish and maintain procedures to ensure that the handling, preservation, and storage of test, inspection, and measurement equipment are performed as to preserve its accuracy and suitability for use.

Art. 101. Each manufacturer shall protect the inspection, test, and measurement facilities and equipment, including test hardware and software, from adjustments that could invalidate the calibration.

Art. 102. Each manufacturer shall establish procedures to assess the impact of previous measurement results when non-conformities in the measurement and test equipment are found, and the result of this assessment shall be documented.

Section V Validation

Art. 103. Special processes shall be validated according to previously established protocols and the results of the validations, including the date and identification of the person responsible for their approval, shall be recorded.

Art. 104. Analytical methods, ancillary process support or environmental control systems, automated computerized systems, and software that may adversely affect product quality or the quality system shall be validated.

Art. 105. Each manufacturer shall establish procedures to periodically verify its validated processes, analytical methods, ancillary process support or environmental control systems, automated computerized systems, and software and, where applicable, establish the frequency for revalidation.

Art. 106. Each manufacturer shall establish a change control procedure to control changes in ancillary systems, software, equipment, processes, methods, or other changes that could influence product quality, including a risk assessment within the risk management process.

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

§ 2 The changes mentioned in the caput of this article shall be formally requested, documented, and approved prior to implementation.

CHAPTER VI

HANDLING, STORAGE, DISTRIBUTION AND TRACEABILITY

Section I

Handling

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

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

Art. 109. The procedures mentioned in art. 107 and art. 108 of this Resolution shall ensure that components, manufacturing materials, intermediate products or finished products:

I - are not used or distributed, when the quality or the condition of suitability for use deteriorates over time;

II - closest to their expiry date are distributed or used first; and III - are not distributed

or used when expired.

Section II

Storage and Distribution

Art. 110. Each manufacturer shall establish and maintain procedures for identifying components, manufacturing materials, intermediate products, finished products, and quality control samples, in order to prevent reversals (exchanges) during storage.

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

Art. 112. Each manufacturer shall maintain distribution records, which include or refer to:

I - name and address of the consignee;

II - identification and quantity of products shipped, with shipping date; and III -

any numerical control used for traceability.

Section III

Identification, traceability and non-conformities

Art. 113. Each manufacturer shall establish and maintain procedures for identifying components, manufacturing materials, intermediate products and finished products during all stages of storage, production, distribution and installation to avoid confusion and to ensure correct service of orders.

Art. 114. Each manufacturer shall identify each unit, batch, or shipping of products with a serial or batch number, and such identification shall be entered in the product history file.

Sole paragraph. Each manufacturer shall identify each unit, batch, or shipping of products with a serial or batch number, and such identification shall be entered in the product history file.

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

Sole paragraph. The procedures referred to in the caput of this article shall contain prescriptions for the identification, documentation, assessment, separation, and disposal of non-conforming components, manufacturing materials, intermediate products, and finished products.

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

Sole paragraph. The results of the assessments and any investigations referred to in the caput of this article shall be recorded.

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

Art. 118. The process of reviewing and disposing of non-conforming components, manufacturing materials, intermediate products, finished products, and returned products shall be described in an established procedure.

§ 1 The disposal of the products mentioned in the caput of this article shall be documented, and a record of the justification and manual or electronic signature of the person responsible for the disposal shall be maintained.

§ 2 In case of authorization for the use of the products mentioned in the caput of this article, the decision shall be based on a technically justifiable risk assessment.

Art. 119. Each manufacturer shall establish and maintain procedures for the rework, reinspection, and re-assessment of intermediate or finished products after rework to ensure that they meet their original specifications.

Sole paragraph. The activities related to rework and re-assessment of the products referred to in the caput of this article, including problems arising from rework, shall be documented in the product history file.

CHAPTER VII

CORRECTIVE AND PREVENTIVE ACTIONS

Section I General Requirements

Art. 120. Each manufacturer shall establish and maintain procedures for:

I - analyzing processes, work operations, quality audit reports, quality records, technical assistance records, complaints, returned products, and other sources of quality data to identify existing and potential causes of non-conformities related to the product, process, or quality system;

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

III - identify and carry out the necessary actions to prevent the occurrence, correct what has happened, and
prevent the recurrence of non-conformities;

IV - verify or validate the effectiveness of the corrective action and ensure that it does not adversely affect the product;

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

VI - ensure that information regarding quality problems or non-conforming products is properly disseminated to those directly involved in maintaining product quality or preventing such problems from occurring;

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

VIII - determine the recall of products and other field actions relevant in the case of products already distributed.

§ 1 The analysis referred to in item I of this article shall be based on a valid statistical technique for detecting recurring quality problems, when applicable.

§ 2 To meet the provisions of item IV of this article, any change made, when applicable, shall follow established change control procedures and validation protocols.

Section II

Complaints Management

Art. 121. Each manufacturer shall establish and maintain procedures for receiving, examining, assessing, investigating and filing complaints, ensuring that:

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

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

III - complaints are examined to verify whether it is necessary to conduct an investigation;

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

V - records are maintained, when an investigation is conducted, containing the following information:

a) product name;

b) date of receipt of the complaint;

c) any control number used;

d) name, address and telephone number of the claimant;

e) nature of the complaint; and

f) date and results of the investigation, including actions taken.

§ 1 When the investigation mentioned in item III of this article is not conducted, the unit shall record the reason why the investigation was not conducted and the name of those responsible for the decision not to investigate.

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

Section III

Quality Audit

Art. 122. Each manufacturer shall conduct and document quality audits to assess conformity of the quality system with the established requirements.

Art. 123. Quality audits shall be conducted by people who are demonstrably trained, in accordance with established auditing procedures, but are not directly responsible for the matters being audited.

Sole paragraph. Those responsible for conducting the quality audit shall not be directly responsible for the matters being audited.

Art. 124. Those responsible for the audited areas shall be notified regarding any non-conformities identified.

CHAPTER VIII

INSTALLATION AND TECHNICAL ASSISTANCE

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

Art. 126. At the time of installation of the product, by the manufacturer or its authorized representative, it shall be verified that the product operates according to established criteria.

Sole paragraph. The results of the verification referred to in the caput of this article shall be recorded.

Art. 127. Each manufacturer shall ensure that installation instructions and procedures are distributed with the product, or are otherwise available to the person responsible for installing the product.

Art. 128. Each manufacturer shall establish and maintain procedures to ensure that finished products submitted to technical assistance by the manufacturer or its representative meet the specifications.

Art. 129. Each manufacturer shall establish and maintain procedures to ensure that technical assistance records are maintained and that they contain:

I - the product purpose of the service;

II - the control number used;

III - the date the service was performed;

IV - the identification of the service provider; V - the description of the service performed; and

VI - the results of inspections and tests for service approval.

Art. 130. Each manufacturer shall periodically review the technical assistance records.

Sole paragraph. In cases in which the analysis referred to in the caput of this article identifies failure trends that pose danger, or records involving death or serious injury, corrective/preventive action shall be initiated according to the requirements of this Resolution.

CHAPTER IX

STATISTICAL TECHNIQUES

Art. 131. Each manufacturer shall establish and maintain procedures to identify valid statistical techniques to verify quality system performance and process capability to meet established specifications.

Art. 132. Sampling plans shall be formalized in writing and based on valid statistical logic.

Art. 133. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are suitable for their intended use and that they are reviewed regularly.

Art. 134. The revision of sampling plans shall take into account the occurrence of product non-conformities, quality audit reports, complaints, and other indicators.

CHAPTER X FINAL

PROVISIONS

Art. 135. The documentation that proves compliance with the requirements set forth in this Resolution shall be available whenever requested by health surveillance agencies.

Art. 136. Non-compliance with the provisions contained in this Normative Instruction constitutes a health infraction, pursuant to Law No. 6.437, of August 20, 1977, without prejudice to the applicable civil, administrative and criminal liabilities.

Art. 137. The following are hereby revoked:

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

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

Art. 138. This Resolution enters into force on May 2, 2022.

ANTONIO BARRA TORRES