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RESOLUTION RDC No. 665, MARCH 30, 2022

Provides for Good Manufacturing Practices for Medical Products and Diagnostic Products for Use in Vitro.

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the powers conferred on it by art. 15, Ili and IV, allied to art. 7, Ili and IV, of Law No. 9,782, of January 26, 1999, and to art. 187, VI, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of 10 of

December 2021, resolves to adopt the following Resolution, as resolved at the Extraordinary Meeting - RExtra No. 6, held on March 30, 2022, and I, Chief Executive Officer, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section 1

Objective

Art. 1 This Resolution provides for Good Manufacturing Practices (GMP) for Medical Products and Diagnostic Products for In Vitro Use, establishing the requirements that describe 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.

§ 1° The requirements mentioned 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 Resolution of the Common Market Group (GMC) MERCOSUR No. 20, of November 17, 2011, MERCOSUR/GMC/RES. No. 20/11, "MERCOSUR Technical Regulation on Good Manufacturing Practices for Medical Products and Diagnostic Products for In Vitro Use (repeal of GMC Res. No. 04/95, 38/96, 65/96 and 131/96)".

Section II

Coverage

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

§ 1. When the manufacturers mentioned in the caput 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.

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

1 - Chapters 1, VII and VIII, in full:

Ii - Chapter Ii, in full, except Section IV:

Ili - Chapter Ili, 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 art. 119.

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

I - Chapters I and VII, in full:

II - Chapter Ii, in full, except Section IV:

III - Chapter Ili, Section 1:

IV - Chapter V, articles 67, 68, 69, 70, 71. 72, 73, 74, 75, 76 and 77: and

V - Chapter VI, in full, except art. 119.

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

1 - Chapters 1, II, VII, VIII and IX in full:

Ii - Chapter Iii, Section I and Section Iii:

III - Chapter IV, art. 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 art. 119.

§ 5° Companies that carry out more than one activity must comply with the specific requirement defined for each activity

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

Section III

Definitions

Art. 3º For the purposes 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 and 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 their results satisfy the specified procedures in your quality system:

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

IV - project input data: description of physical attributes, indication of use, performance, compatibility, safety, efficacy, ergonomics, usability, information from previous projects and risk management results, among other requirements of a medical product or product for in vitro diagnostic use, which are used as the basis of your project:

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

VI - damage: Physical injury or damage to the 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 must comply with:

VIII - establish: define, document in writing or electronically, and implement:

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

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

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

XIi - batch or batch: quantity of a product made in a manufacturing or sterilization cycle, whose essential characteristic is homogeneity;

XIIi - manufacturing material: material or substance used in the manufacturing process or to facilitate this process, including cleaning agents, mold release agents, lubricating oils, sterilants, or

even other by-products of the manufacturing process;

XIV - non-compliance: non-compliance with a previously specified requirement;

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

XVI - danger: potential source of harm;

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

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

XIX - production: all operations involved in the manufacture of a given product, from the receipt of 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: totality of aspects and characteristics that enable a medical product or in vitro diagnostic product to meet the requirements of suitability for use, including safety and performance;

XXII - complaint: written, oral or electronic communication, regarding the non-acceptance of the identity, quality, durability, reliability, safety, efficacy or performance of a product;

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

XXIV - product history record: compilation of records containing the complete history of the production of a finished product;

XXV - project history record: compilation of documents containing the complete project history of a finished product;

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

XXVII - rework: part or all of the manufacturing operation intended to correct the non-compliance of a component, intermediate product or finished product, so that it meets the specifications defined in the RMP;

XXVIII - project review: documented, systematic and complete examination carried out during the development of the project to assess its adequacy to the planning and established objectives;

XXIX - risk: combination between probability of occurrence and severity of damage;

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

XXXI - validation: confirmation by analysis and objective evidence that the requirements defined for a given 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 compliance with established specifications; and

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

§ 1° The procedures mentioned in subsection Ii of the caput of this article must be implemented efficiently and adequately to achieve the objectives of the quality system.

§ 2° The quality audit referred to in item Ii of the caput of this article is different from other activities of the quality system required by this Resolution.

§ 3 With respect to 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 With respect to 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 satisfies the predetermined specifications.

CHAPTER II

GENERAL REQUIREMENTS OF THE QUALITY SYSTEM

Section I

General requirements

Art. 4th Each manufacturer must 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 the intended use.

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

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

Ii - establish procedures to comply with the legal provisions provided for in current health legislation.

Section I

Managerial Responsibility Subsection 1

Quality policy

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

Art. 6° Executive management must maintain the quality policy at all levels of the organization.

Art. 7° Executive management must ensure that the quality policy is described in a quality manual and that it is understood by all employees who may affect or influence the quality of a product.

subsection I

Organization and responsibilities Art. 8° Each manufacturer must:

I - establish and maintain an adequate organizational structure, represented by an organizational chart, with sufficient personnel 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, execute and verify the work related to quality, with the necessary independence to carry out their responsibilities; and

III - establish verification functions, provide adequate resources and designate trained personnel to perform verification activities.

Art. 9° The executive management of each manufacturer must designate an individual from the executive management itself, who, regardless of other functions, has authority and responsibility to:

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

II - reporting quality system performance to executive management for review and providing information on quality system improvement.

Single paragraph. The designation referred to in the caput of this article must be documented.

Subsection III

management review

Art. 10. The executive management of each manufacturer must evaluate the adequacy 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 that it complies with the objectives of the established quality policy.

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

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

Section III

Personal

Art. 13. Each manufacturer must have a sufficient number of personnel with instruction, 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 must be maintained.

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

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

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

§ 3° Staff training must be documented.

Art. 16. Each manufacturer must ensure that any consultant who advises on methods employed or controls used for the design, purchase, manufacture, packaging, labeling, storage, installation or service of products, has sufficient qualifications - education, training and experience - to advise on the subjects for which he was hired.

Art. 17. The hiring of consultants must be conducted in accordance with the procurement 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 encompasses the entire lifecycle of a medical device or in vitro diagnostic device, from conception to discontinuation, to:

I - identify the associated hazards;

II - estimate and assess the risks involved;

III - control the associated risks; and

IV - to evaluate the effectiveness of the established controls.

Art. 19. The ongoing risk management process must include the following elements:

I - analysis;

II - evaluation;

III - control; and

IV - risk monitoring.

Art. 20. The company's executive management must designate the responsible professionals, 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

Purchase 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, conform to specifications.

Single paragraph. Each manufacturer must ensure that the services performed by third parties mentioned in the caput of this article comply with the specifications established by it.

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

Art. 23. Each manufacturer must evaluate and select potential suppliers, according to their ability to meet the requirements previously established, maintaining a register of approved suppliers.

Single paragraph. Records of supplier evaluation and results must be maintained.

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

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

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

Art. 27. Approval of purchase orders, including the date and manual or responsible electronics. must be documented.

CHAPTER III

QUALITY DOCUMENTS AND RECORDS

Section I

General requirements

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

Art. 29. Each manufacturer must designate people to evaluate and approve all documents established in this Resolution for adequacy before their issuance.

Single 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, must be documented.

Art. 30. Each manufacturer shall ensure that all documents are current 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 must be evaluated, documented, reviewed and approved by persons whose role and level of responsibility are equivalent to those who performed the original review and approval.

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

I - the description of the change:

II - the identification of the altered documents:

III - the identification of the affected documents:

IV - the identification of the person responsible for the alteration:

V - the date of approval of the change: and

VI - the date on which the change takes effect.

Art. 33. A list of current documents must be maintained, in order to identify the current status of documents and ensure that only current and approved documents are in use.

Art. 34. All quality documents and records must be legible and stored in a way that minimizes damage, prevents loss and provides rapid recovery.

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

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

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

Section II

Product history record

Art. 38. Each manufacturer must maintain historical records of products.

Art. 39. Each manufacturer shall establish and maintain procedures to ensure that historical records of products are maintained for each batch or series, in order to demonstrate that the products were manufactured in accordance with the product master record and the requirements of this Resolution.

Art. 40. The product's historical record must include, or make reference to, the following information:

I - date of manufacture:

II - components used:

III - quantity manufactured;

IV - results of inspections and tests:

V - parameters of special processes:

VI - quantity released for distribution:

VII - labeling:

VIII - identification of the serial number or production batch: and IX - final product release.

Section III

Inspection and testing records

Art. 41. Each manufacturer must keep a record 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 inspections and tests established must include the acceptance criteria, the results, the equipment/instrument used and the date and manual or electronic signature of the person in charge.

CHAPTER IV

PROJECT CONTROL AND PRODUCT MASTER REGISTRATION (RMP)

Section I

Project Control

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

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

§ 1° The plans mentioned in the caput of this article must include any interaction between the various organizational and technical groups that have some interface with the project.

§ 2 The plans mentioned in the caput of this article must be evaluated, updated and approved, as the development of the project progresses.

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

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

Art. 46. Project input data must be documented, evaluated and approved by a qualified designee.

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

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

§ 1 The design verification must be carried out by a designated person and must ensure that the project output data satisfies the input data.

§ 2° The results of the project verification, including the identification of the verified project, the verification methods, the date and the name of the person in charge of the verification, must be documented in the historical record of the project.

Art. 49. Each manufacturer shall 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.

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

§ 2 The project output data must be documented, reviewed and approved before its release.

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

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

Art. 51. The results of the design review must be documented in the historical record of the project.

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

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

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

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

Art. 56. Design validation should include software validation where appropriate.

Art. 57. The results of project validation, including identification, methods, date, and manual or

electronic signature of those responsible, must be documented in the project's historical record.

Art. 58. In design validation, stability studies must be carried out whenever applicable.

Art. 59. Each manufacturer must ensure that the design is released for production only when approved by the persons designated by the manufacturer.

§ 1 The designated persons, mentioned in the caput of this article, must review all records required for the historical record of the project, in order to ensure that it is complete and that the final project is compatible with the approved plans, before its release. .

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

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

Art. 61. Each manufacturer must establish and maintain a historical design record for each product.

Single paragraph. The project history record must contain or reference all records necessary to demonstrate that the project was developed in accordance with the approved project plan and the requirements of this resolution.

Section I

Product Master Record (PMR)

Art. 62. Each manufacturer must maintain product master records (RMPs).

Art. 63. The RPM for each product type must include or reference 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 production environmental specifications:

II - 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 must design, conduct, control and monitor all production processes in order to ensure that the product conforms to its specifications.

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

Single paragraph. Process controls should be established at any step where deviation from product specifications may occur as a result of the manufacturing process.

Art. 66. Process controls must include:

I - documented instructions, standard operating 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 norms, standards or reference codes; and

IV - instructions for Release of the beginning of the process.

Art. 67. The company's facilities must be properly designed to:

I - ensure adequate flow of people:

II - provide for the performance of all operations; and

III - prevent exchanges or contamination of components, manufacturing materials, intermediate and finished products, and ensure the correct handling of these materials.

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

Single paragraph. For the purposes of the caput of this article, the correct functioning of the established environmental control systems must be monitored, keeping the corresponding records.

Art. 69. Each manufacturer must establish and maintain adequate Cleaning and Sanitization procedures. as well as a schedule that satisfies the requirements of the manufacturing process specifications.

Single paragraph. Each manufacturer must ensure that the personnel involved understand the Cleaning and Sanitization procedures.

Art. 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.

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

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

Art. 72. Each manufacturer must limit food and beverage consumption to specific locations so as not to affect 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 must be established and it must 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 by-products must occur in accordance with applicable legislation in force.

Art. 76. Biological safety standards must be observed in cases where there is a risk biological.

Art. 77. Each manufacturer must ensure compliance with applicable standards related to workers' health, including the use of personal protective equipment that is compatible with the work processes carried out.

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

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

Single paragraph. The maintenance program must be in a location that is easily accessible to personnel responsible for the maintenance and use of the equipment.Art. 80. As atividades de manutenção devem ser registradas, com a data de realização e a identificação das pessoas encarregadas.

Art. 81. Each manufacturer shall ensure that any acceptable tolerances or inherent limitations are posted in a conspicuous location on or near equipment requiring periodic adjustments, or 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 such materials are removed from the product or limited to a specified quantity that does not adversely affect the quality of the product.

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

Single paragraph. Critical parameters of special processes must be monitored and recorded in the product history record.

Section II

Packaging controls, labeling and instructions for use

Art. 84. Each manufacturer must 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 must 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 must ensure that labels are designed, printed and, where applicable, applied in such a way that they remain legible and adhered to the product during processing, storage, handling and use.

Art. 87. Labels and instructions for use must not be released for use until an authorized person has examined their compliance with the information contained therein.

§ 1° The approval of labels and instructions for use must be documented in the product's historical record, including the date, name and manual or electronic signature of the person in charge.

§ 2° In the case of importers, the approval documentation referred to in § 1 of this article may be registered in a specific document in lieu of the product's historical record.

Section III

inspection and testing

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

Art. 89. Conformity to specified requirements must be evaluated upon receipt of components and manufacturing materials, as well as at intermediate stages of production and final acceptance of the finished product.

§ 1° The results of the activities mentioned in the caput of this article must be documented, including their conclusion - acceptance or rejection.

§ 2 The authority and responsibility for carrying out the activities mentioned in the caput of this article must be defined by the manufacturer.

Art. 90. Incoming components and manufacturing materials, 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.

Art. 91. Each manufacturer shall 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.

Art. 92. Finished products may only be released when the activities specified in the RMP 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.

Single paragraph. The release of finished products must be documented, including the date and manual or electronic signature of the person in charge.

Section IV

Measuring and testing equipment

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

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

Art. 95. Each manufacturer must establish and maintain calibration procedures that include specific guidelines and limits of precision and accuracy, as well as prescriptions for corrective actions, when the limits of precision and accuracy are not reached.

Art. 96. Calibration must be performed by personnel who have the necessary education, training, practice and experience.

Art. 97. Measuring and testing equipment must be identified in order to enable the calibration status to be determined.

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

Single paragraph. When there is no applicable calibration standard available, the manufacturer must establish and maintain its own standard.

Art. 99. Cada fabricante deve assegurar que sejam mantidos registros das datas de calibração, das mensurações obtidas, do responsável encarregado desta tarefa e da data seguinte para esta operação.

§ 1° Os registros mencionados no caput deste artigo devem ser mantidos pelo fabricante.

§ 2° Os registros mencionados no caput deste artigo devem estar disponíveis para o pessoal que utiliza o equipamento e para os responsáveis pela sua calibração.

Art. 100. Cada fabricante deve estabelecer e manter procedimentos para assegurar que o manuseio, a preservação e a guarda de equipamentos de teste, inspeção e medição sejam feitos de forma a preservar sua precisão e adequação ao uso.

Art. 101. Cada fabricante deve proteger as instalações e os equipamentos de inspeção, teste e medição, incluindo hardware e software de teste, de ajustes que possam invalidar a calibração.

Art. 102. Cada fabricante deve estabelecer procedimentos para avaliar o impacto dos resultados de medições anteriores quando constatar não conformidades no equipamento de medição e teste, e o resultado desta avaliação deve ser documentado.

Section V

Validation

Art. 103. Special processes must 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, must be recorded.

Art. 104. Analytical methods, auxiliary process support systems or environmental control. Automated computer systems and software that could adversely affect product quality or the quality system must be validated.

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

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

§ 1 The procedure referred to in the caput of this article must 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 must be formally requested, documented and approved before implementation.

CHAPTER VI

HANDLING, STORAGE, DISTRIBUTION AND TRACEABILITY

Section I

Handling

Art. 107. Each manufacturer must 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 the handling.

Art. 108. Each manufacturer must establish and maintain procedures to identify the 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 must ensure that components, manufacturing materials, intermediate products or finished products

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

II - closer to maturity are distributed or used first: and

III - are not distributed or used, with an expired period of validity.

Section II

storage and distribution

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

Art. 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.

Art. 112. Each manufacturer must maintain distribution records that include or reference:

1 - the name and address of the consignee;

li - the identification and quantity of products shipped, with shipping date; and

Ili - to any numerical control used for traceability. Section III

Identification, traceability and non-conformities

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

Art. 114. Each manufacturer must identify each unit, batch or batch of products with a serial or batch number and this identification must be entered into the product's historical record.

Single paragraph. In the case of distributors, warehouses and importers, the identification referred to in the caput of this article can be registered in a specific document in lieu of the product's historical record.

Art. 115. Each manufacturer must establish and maintain procedures to ensure that components, manufacturing materials, intermediate products, finished products and returned products that do not conform to established requirements are not inadvertently used or installed.

Single paragraph. The procedures referred to in the caput of this article must contain requirements for the identification, documentation, evaluation, segregation and disposal of components, manufacturing materials, intermediate products and non-conforming finished products.

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

Single paragraph. The results of the evaluations and eventual investigations mentioned in the caput of this article must be recorded.

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

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

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

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

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

Single paragraph. Activities related to rework and reassessment of the products mentioned in the caput of this article, including problems arising from rework, must be documented in the product history record.

CHAPTER VII

CORRECTIVE AND PREVENTIVE ACTIONS

section 1

General requirements

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

1 - analyze processes, work operations, quality audit reports, quality records, technical assistance records, complaints, returned products and other sources of quality data, in order to identify existing and potential causes of product-related nonconformities , process or quality system;

li - investigate the cause of non-conformities related to the company's product, process or system quality;

Ili - identify and execute the necessary actions to prevent the occurrence, correct the occurrence and

prevent the recurrence of nonconformities:

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

V - record activities related to corrective and preventive actions:

VI - ensure that information about 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 about identified quality problems and preventive and corrective actions to the executive management for knowledge and monitoring, as well as to the competent health authority, when applicable: and

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

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

§ 2° In order to comply with the provisions of item IV of this article, any alteration carried out, when applicable, must observe alteration control procedures and established validation protocols.

Section I

Complaints management

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

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

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

III - complaints are examined to see if it is necessary to conduct an investigation:

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

V - records are kept, 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 complainant:

e) nature of the claim; 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 must record the reason why the investigation was not carried out and the name of those responsible for the decision not to investigate.

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

Section III

Quality audit

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

Art. 123. Quality audits must be conducted by demonstrably trained persons, in accordance with established audit procedures. but who do not have direct responsibility for the matters being audited.

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

Art. 124. Those responsible for the audited areas must be notified of identified non-conformities.

CHAPTER VIII

INSTALLATION AND TECHNICAL ASSISTANCE

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

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

Single paragraph. The results of the verification mentioned in the caput of this article must be recorded.

Art. 127. Each manufacturer must 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 for service by the manufacturer or his representative meet specifications.

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

I - the product object of the service;

II - the control number used:

II - the date of performance of the service:

IV - the identification of the service provider:

V - the description of the service performed: and

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

Art. 130. Each manufacturer should periodically review service records.

Single paragraph. In cases where the analysis referred to in the caput of this article identifies failure trends that represent danger, or records involving death or serious injury, corrective/preventive action must 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 the performance of the quality system and the ability of the process to meet established specifications.

Art. 132. Sampling plans must 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 regularly reviewed.

Art. 134. The review of sampling plans should consider the occurrence of product nonconformities, quality audit reports, complaints and other indicators.

CHAPTER X FINAL PROVISIONS

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

Art. 136. Failure to comply with the provisions contained in this Resolution constitutes a sanitary infraction, under the terms of Law No. 6,437, of August 20, 1977, without prejudice to applicable civil, administrative and criminal liabilities.

Art. 137. The following are hereby revoked:

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

Ii - Normative Instruction - IN No. 8, of December 26, 2013, published in the Federal Official 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

ACTION PLAN

1. **PROCEDURES/MANULA AND DOCS TO BE REVIEWED: 34**
   DEADLINE: APRIL 29TH, 2022

Identificação	DESCRIÇÃO	Revisão
***	Política da Qualidade, Missão, Visão e Valores	3.0
MBP-001	Manual de Boas Práticas do Sistema de Gestão da Qualidade da Orthofix do Brasil	1.0
PGRSS	Plano de Gerenciamento de Resíduos de Serviço de Saúde	2.0
***	Nomeação do Representante da Gerência Executiva	4.0
POP-QUA-001	Elaboração, Controle de Documentos e Registros	0.0
POP-RH-002	Gestão de Recursos Humanos	0.0
POP-QUA-003	Homologação de Fornecedores & Distribuidores	0.0
POP-QUA-004	Identificação e Rastreabilidade	0.0
POP-OPER-005	Recebimento, Armazenamento e Manuseio de Produtos	0.0
POP-OPER-006	Distribuição e Transporte	0.0
POP-QUA-007	Auditoria Interna	0.0
POP-QUA-008	Reclamação de Cliente	0.0
POP-QUA-009	Tratamento de Não Conformidades	0.0
POP-QUA-010	Ação Corretiva e Preventiva	0.0
POP-QUA-011	Análise Crítica e Desempenho	0.0
POP-QUA-012	Embalagem e Rotulagem	0.0
POP-OPER-013	Atendimento de Cirurgias	0.0
POP-OPER-014	Separação e Expedição	0.0
POP-OPER-015	Cadastro de Novos Produtos	0.0
POP-QUA-016	Tecnovigilância e Recall	0.0
POP-TI-017	Backup	0.0
POP-OPER-018	Atendimento aos Distribuidores	0.0
POP-FN-019	Faturamento	0.0
POP-OPER-020	Compras	0.0
POP-QUA-021	Gerenciamento de Registro de Produtos	0.0
POP-QUA-022	Limpeza, Sanitização e Controle Ambiental	0.0
POP-QUA-023	Devolução de Produtos	0.0
POP-QUA-024	Gerenciamento de Risco	0.0
POP-OPER-025	Política de Inventário	0.0
POP-QUA-026	Técnicas Estatísticas	0.0
POP-QUA-007	Controle de Validade de Produtos Estéreis	00
IT-PADR-001	Virada de Saldo e Fechamento de Estoque	0.0
IT-PADR-002	Rastreabilidade Lotes Internos	03
IT-PADR-003	Criação de PO (Purshase Order)	1.0

2. **REQUEST A NEW DISTRIBUTION LETTER: THE NEW LETTER MUST BE RELEASED UNTIL APRIL 29TH, 2022 – NEW PRODUCT REGISTRATION CANNOT BE PERFORMED UNTIL THE DOCUMENT HAS BEEN UPDATED.**

3. **MDSAP CERTIFICATION MUST BE BASED ON RDC 665/22.**