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Ministry of Health/Brazilian Health Regulatory Agency/Collegiate Board

COLLEGIATE BOARD RESOLUTION – RDC NO. 687 OF 13 MAY 2022

Establishes criteria for granting or renewing the Certification of Good Manufacturing Practices for Medical Devices.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, item III, and Article 15, items III and IV, of Law no. 9,782 of 26 January 1999, and item VI, paragraph 1 of Article 187 of the Internal Regulation approved by Collegiate Board Resolution - RDC No. 585, of December 10, 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on May 12, 2022, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Object

Article 1. This Resolution provides for inspection programs and establishes criteria for granting and renewing the Certification of Good Manufacturing Practices for Medical Devices, in addition to the general provisions of administrative procedures for granting the Certification of Good Manufacturing Practices.

Section II

Scope

Article 2. This Resolution applies to the granting and renewal of the Certification of Good Manufacturing Practices for Medical Devices to manufacturing establishments that meet the criteria defined in this Resolution and other applicable regulations.

Article 3. The manufacturing units of medical devices of risk classes III and IV that fit one of the conditions below shall be subject to the Certification of Good Manufacturing Practices for Medical Devices by Anvisa:

I - manufacturing unit that produces a final product on its behalf or for another company.

II - manufacturing unit that performs the final release of the final product, associated with at least one production stage, excluding design, distribution, sterilization, packaging, and labelling.

III - medical software manufacturing unit (Software as a Medical Device – SaMD).

Paragraph 1. The packaging activity considered as a sterile barrier system for products declared as sterile is considered as a production stage subject to certification of good manufacturing practices for the purposes provided for in item II.

Paragraph 2. The manufacturing units of medical devices for *in vitro* diagnostics that perform the stages of impregnation, lamination, or cutting of immunochromatography strips are subject to certification of good manufacturing practices under the terms of item II.

Section III

Definitions

Article 4. For the purposes of this Resolution, the following definitions are adopted:

I - legal manufacturer: legal entity, either public or private, responsible for the design, manufacture, packaging, and labelling of a product, with the intention of making it available for use under its name, such operations being carried out by the company itself or by third parties on its behalf.

II - final release: final approval of the batch or series of the finished product by a person formally designated to ensure that the acceptance criteria have been met.

III - final product: it is the product subject to regularization that is fit for use or functionally complete, whether or not it is packaged, labelled, or sterilized.

IV - finished product: finished product that has gone through all production stages, including labelling, final packaging, and sterilization (when applicable).

V - inspection report: report that describes the company's situation regarding compliance with the good manufacturing practices, in accordance with the standards referred to in the scope of the report.

VI - manufacturing unit: site where one or more manufacturing stages take place, which may be the legal manufacturer itself, contracted manufacturer, or original product manufacturer.

CHAPTER II

DOCUMENTS FOR SUBMISSION

Article 5. The processes for granting the Certification of Good Manufacturing Practices referred to in this Resolution must include the following documents:

I - specific petition form for the Certification of Good Manufacturing Practices for Medical Devices, duly completed.

II - general production flowchart related to the manufactured products, identifying which stages are performed in the facility undergoing the certification process.

III - layout of the facility undergoing the certification process, including the floor plan of the manufacturing unit.

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IV - list of all products subject to health regularization in Brazil produced in the manufacturing unit undergoing the certification process, including technical name, production line (equipment, materials, or medical devices for *in vitro* diagnostics) and respective risk class, which are or will be commercialized in Brazil under the respective trade name.

V - statement indicating whether the products that are or will be commercialized in Brazil are regulated in the country of origin and countries that are members of MERCOSUR and IMDRF.

VI - list of all inspections or regulatory audits carried out in the establishment undergoing the certification process in the last 3 (three) years, indicating the period of each inspection or audit; name of the authority or auditing organization responsible for it; conclusion and details of any resulting regulatory action.

VII - copy of the inspection report used to prove compliance with the good manufacturing practices to the health authority of the country of origin or document attesting compliance with the good manufacturing practices in the country of origin, when applicable.

VIII - copy of the inspection report issued by the health authority of a country that is a member of a specific audit program recognized by Anvisa or a statement confirming that the company participates in a specific audit program recognized by Anvisa, when applicable.

Paragraph 1. For the purposes of the provisions in item IV, the product with the highest risk class manufactured in the manufacturing unit undergoing the certification process must be informed, even if it is not object of commercialization in Brazil.

Paragraph 2. For domestic manufacturers, only items I to IV are applicable, and inspection reports must be submitted by the local – state or municipal – health authorities, through a specific system, and may be replaced by a statement confirming that the manufacturing unit participates in a specific audit program recognized by Anvisa.

Paragraph 3. For manufacturers located in Mercosur member countries, only items I to V apply, and inspection reports must be forwarded by the local health authorities, and may be replaced by a statement confirming that the manufacturing unit participates in a specific audit program recognized by Anvisa.

Paragraph 4. For manufacturers participating in a specific audit program recognized by Anvisa, only items I to VI are applicable, and the audit reports must be made available by the respective Auditing Organization.

Paragraph 5. The procedures for recognition of the Auditing Organization are provided for in Resolution – RE No. 392 of 20 February 2018.

Article 6. The processes for renewing the Good Manufacturing Practices Certificate referred to in this Resolution must include all the documents listed in Article 5, except documents II, III, IV, and V, which should only be submitted in case of alteration in their contents.

Article 7. The manufacturing establishment undergoing the certification process has the option to send directly to Anvisa the documents described in items III to VIII of Article 5, provided that they are properly identified and submitted in addition to the process it relates to.

Sole paragraph. The deadline to submit the documents referred to in the caption of this article is up to 30 (thirty) days after the date of submission of the certification petition.

CHAPTER III

GRANTING OF CERTIFICATES OF GOOD MANUFACTURING PRACTICES

GENERAL PROVISIONS

Article 8. The granting and renewal of the Certificate of Good Manufacturing Practices for Medical Devices of risk classes III and IV may occur through one of the following situations:

I - upon assessment of the documents listed in items I to VI of Article 5 of this Resolution for companies that have an audit report issued by an Auditing Organization participating in a specific audit program recognized by Anvisa.

II - upon assessment of the documents listed in Article 5 of this Resolution and a risk assessment that justifies the issuance of the Good Manufacturing Practices Certificate.

III - upon assessment of the inspection report issued by Anvisa as a result of the on-site inspection, motivated by the risk analysis or by the absence of an audit report under the terms of Article 5 of this Resolution.

Article 9. For the granting and renewal of certification through the mechanisms provided for in item I of Article 8, the audit reports must have been issued up to 3 (three) years before the date of submission, cover the risk classes and production lines requested in the ongoing certification process, and allow the conclusion that the establishment complies with the Good Manufacturing Practices.

Paragraph 1. In case of non-conformities listed in the audit reports, the action plans must be forwarded to Anvisa by the respective Auditing Organization.

Paragraph 2. If the non-conformities presented in the report are open, a requirement shall be imposed to the petitioner; once the submission of the listed items is not complied with, the certification request shall be rejected.

Article 10. The granting and renewal of certification through the mechanism provided for in item II of Article 8 shall be carried out through a risk assessment tool published on Anvisa website, which considers the result of the assessment of the documents listed in Article 5, the complexity of the manufacturing unit, the technologies involved, the intrinsic risk of the products, and the indication of use, among other characteristics.

Paragraph 1. In case of non-conformities listed in the inspection or audit reports, action plans must be submitted, having been analyzed and deemed satisfactory by the issuer, or the company must present proof of implementation of corrective actions.

Paragraph 2. If the non-conformities presented in the report are open, a requirement shall be imposed to the petitioner; once the submission of the listed items is not complied with, the certification request shall be rejected.

Article 11. The granting and renewal of certification through the mechanism provided for in item III of Article 8 shall result from the elimination of the possibilities provided for in items I and II of Article 8.

CHAPTER IV

INSPECTION PROGRAMS

Article 12. Anvisa may verify compliance with the Good Manufacturing Practices for Medical Devices through specific inspection programs.

Paragraph 1. The programs mentioned in the caption of this article refer to a set of actions carried out for inspection purposes in manufacturing units of products granted marketing authorization by Anvisa.

Paragraph 2. The programs shall take place regardless of the certification processes.

Paragraph 3. The programs shall be defined based on a health risk assessment that considers the intrinsic risk of the products, the complexity of the manufacturing processes, the technologies involved, the inspection historical data, monitoring, and marketing authorization of the products.

Paragraph 4. The inspection programs may be extended to domestic and international manufacturers, as well as those located in other Mercosur member countries.

Paragraph 5. The programs shall be planned considering the operational capacity of the Agency to carry out inspections, and they shall be assessed, reviewed, and published on a yearly basis.

Paragraph 6. The audit reports issued under the Medical Devices Single Audit Program (MDSAP) shall also be used to verify compliance with the Good Manufacturing Practices through the programs referred to in this chapter.

CHAPTER V

TRANSITIONAL AND FINAL PROVISIONS

Article 13. For all purposes, Anvisa considers reports issued by Auditing Organizations through a specific audit program as evidence of compliance with the good manufacturing practices and production of the effects resulting from it.

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Article 14. The certification issued based on the documentation provided for in Paragraphs 1 and 2 of Article 9 does not exempt the company from receiving an on-site inspection by Anvisa, at any time, even during the validity of the Certificate of Good Manufacturing Practices granted.

Sole paragraph. The imposition of an obstacle by the establishment to receive the on-site inspection from Anvisa, including requests to alter the date unilaterally motivated by the establishment and not accepted by Anvisa, shall lead to cancellation of the Good Manufacturing Practices Certificate.

Article 15. A maximum period of 180 (one hundred and eighty) days is hereby established for requesting the Certification of Good Manufacturing Practices for new manufacturing units covered by Article 3 of this Resolution.

Article 16. Collegiate Board Resolution – RDC no. 183, of 17 October 2017, published on the Federal Official Gazette no. 201 of 19 October 2017, Section 1, page 27, is hereby revoked.

Article 17. This Resolution enters into force on June 1, 2022.

ANTONIO BARRA TORRES

Director-President

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