Ministry of Health - MS
National Health Surveillance Agency – ANVISA

COLLEGIATE BOARD RESOLUTION - RDC No. 687, OF MAY 13, 2022

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

The **Collegiate Board of the National Health Agency**, in the exercise of the attribution granted by art. 7, item III, and art. 15, items III and IV, of Law No. 9.782, of January 26, 1999, and to art. 187, VI, § 1, of the Internal Regulations approves by the Collegiate Board Resolution – RDC No. 585, of December 10, 2021, resolves to adopt the following Resolution, as resolved in meeting held on May 12, 2022, and I, President-Director, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Art. 1 This Resolution provides for the inspection programs and establishes criteria for granting and renewing of 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

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

Art. 3 The manufacturing sites of risk classes III and IV medical devices classified in one of the following conditions will be subject to Certification of Good Manufacturing Practices of Medical Devices by Anvisa:

I - manufacturing site that produces a final product on its behalf or for another company;

II - manufacturing site that performs the final release of the final product, associated with at least one production step, excluding design, distribution, sterilization, packaging and labeling steps;

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

§ 1 The packaging activity considered as a sterile barrier system for products declared as sterile is considered as production step subject to certification of good manufacturing practices for the purposes of the provisions of item II.

§ 2 The manufacturing units of medical devices for in vitro diagnostic that perform the steps of impregnation, lamination or cutting of immunochromatography strips are subject to certification of good manufacturing practices pursuant to item II.

Section III

Definitions

Art. 4 For the purpose of this Resolution, the following definitions are adopted:

I - legal manufacturer: legal entity, public or private, with responsibility for the design, manufacture, packaging and labeling of a product, with the intention to make it available for use under its name, these operations being carried out by the company itself or by third parties on its behalf;

II - final release: final approval of the finished product batch or series by a person formally designated to ensure that 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 packaged, labeled or sterilized;

IV - finished product: finished product that has gone through all steps of the production, including labeling, final packaging and sterilization (when applicable);

V – inspection report: report that describes the company's situation regarding the compliance with the good manufacturing practices, according to the standard referenced in the scope of the report;

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

CHAPTER II

PETITION DOCUMENTS

Art. 5 The processes of granting the Certification of Good Manufacturing Practices referred to in this Resolution must be instructed with the following documents:

I - specific petition form for the Certification of Good Manufacturing Practices of Medical devices, duly filled;

II - general production flowchart related to the products manufactured, identifying which steps are performed in the establishment object of the certification;

III - layout of the establishment object of the certification, including the floor plan of the manufacturing site;

IV - list of all products subject to sanitary regularization in Brazil manufactured in the manufacturing site object of the certification, containing technical name, line (equipment, materials or in vitro diagnostic medical devices) and respective risk class, which are or will be commercialized in Brazil with the respective commercial name;

V - declaration indicating whether the products that are or will be commercialized in Brazil are regularized in the country of origin and countries that are part of MERCOSUL and IMDRF;

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

VII - copy of the inspection report used to prove the compliance with good manufacturing practices before the health authority of the country of origin or document attesting the 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 member of a specific audit program recognized by Anvisa or declaration attesting that the company is a participant in a specific audit program recognized by Anvisa, when applicable.

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

§ 2 For the national manufacturers, only items I to IV apply, and inspection reports must be sent by state or municipal health authorities, through a specific system, and may be replaced by proof that the manufacturing site is a participant in specific audit program recognized by Anvisa.

§ 3 For manufacturers located in countries member of Mercosul, only items I to V apply, and the inspection reports must be sent by local health authorities, and can be replaced by proof that the manufacturing site is a participant in specific audit program recognized by Anvisa.

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

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

Art. 6 The Good Manufacturing Practices Certification renewal processes referred to in this Resolution must be instructed with all the documents listed in art. 5, except for the documents II, III, IV and V, which should only be instructed in the event of a change in their contents.

Art. 7 The manufacturing establishment subject to certification is authorized to send directly to Anvisa the documents referred to in items III to VIII of art. 5, provided that they are duly identified and in addition to the process to which it relates.

Single paragraph. The deadline for filing the documents mentioned in the caput is up to 30 (thirty) days after the date of filing the certification petition.

CHAPTER III

GRANTING OF GOOD MANUFACTURING PRACTICES CERTIFICATES

GENERAL PROVISIONS

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

I - upon evaluation of the documents listed in items I to VI of art. 5 of this Resolution for companies that have an audit report issued by auditing organizations within the scope of a specific audit program recognized by Anvisa;

II - upon evaluation of the documents listed in art. 5 of this Resolution and conducting a risk analysis that justifies the issuance of the Good Manufacturing Practices Certificate;

III - upon evaluation of inspection report issued by Anvisa as a result of carrying out an on-site inspection, motivated by conducting a risk analysis or by the absence of an audit report pursuant to art. 5 of this Resolution.

Art. 9 For the granting and renewal of the certification by the mechanism provided for item I of art. 8, the audit reports must have been issued up to 3 (three) years before the date of protocol, cover the risk classes and production lines subject to the certification request and allow it to be concluded that the establishment complies with the good manufacturing practices.

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

§ 2 If the non-conformities presented in the report are open, a demand will be made to the applicant that, once the submission of the listed items is not complied with, the petition will be rejected.

Art. 10. The granting and renewal of the certification by the mechanism provided for in item II of art. 8 will be carried out through a risk analysis tool published on the Anvisa Portal that considers the result of the evaluation of the documents listed in art 5, manufacturing site complexity, technologies involved, intrinsic risk of the product and the indication of use, among other characteristics.

§ 1 In case of non-conformities listed in inspection or audit reports, action plans must be submitted, analyzed and deemed satisfactory by the issuer or proof of completion of corrective actions.

§ 2 If the non-conformities presented in the report are open, a demand will be made to the applicant that, once the submission of the listed items is not complied with, the petition will be rejected.

Art. 11. The granting and renewal of the certification by the mechanism provided for in item III of art. 8 will result from the elimination of the possibilities provided for items I and II of art. 8.

CHAPTER IV

INSPECTION PROGRAMS

Art. 12. Anvisa's operation in verifying compliance with Good Manufacturing Practices of Medical Devices may occur through specific inspection programs.

§ 1 The programs referred to in the caput of this article refer to a set of actions carried out for inspection purposes in manufacturing sites of products registered with Anvisa.

§ 2 The programs will take place independently of the certification processes.

§ 3 The programs will be defined based on a health risk analysis that considers the intrinsic risks of the products, the complexity of the manufacturing processes, the technologies involved, the historical data of inspection, monitoring and registration of the products.

§ 4 Inspection programs may be extended to national and international manufacturers and those located in other Mercosul member countries.

§ 5 The programs will be planed considering the operational capacity of the Agency to carry out inspections and will be evaluated, reviewed and published annually.

§ 6 The audit reports issued under the Medical Device Single Audit Program will also be used to verify compliance with the Good Manufacturing Practices through the programs addressed in this chapter.

CHAPTER V

FINAL AND TRANSITIONAL PROVISIONS

Art. 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 this.

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

Single paragraph. The imposition of an obstacle by the establishment to receive the on-site inspection by Anvisa, including requests to change the date unilaterally motivated by the establishment and not accepted by Anvisa, will lead to the cancellation of the Good Manufacturing Practices Certification.

Art. 15. A maximum period of 180 (one hundred and eighty) days is established for requesting the Certification of Good Manufacturing Practices for new manufacturing sites covered by art. 3 of this resolution.

Art. 16. The Collegiate Board Resolution – RDC No. 183, of October 17, 2017, published in the Federal Official Gazette No. 201, of October 19, 2017, Section 1, p. 27, is revoked.

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

ANTONIO BARRA TORRES
President-Director