RDC RESOLUTION No. 687, MAY 13, 2022

Establishes the criteria for the grant or renewal of the Certification of Good Manufacturing Practices for Medical Devices.

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the powers conferred on it by arts. 7, item III, and 15, items III and IV of Law No. 9,782, January 26, 1999, and art. 187, VI, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, on December 10, 2021, resolves to adopt the following Resolution, as decided at a meeting held on May 12, 2022, and I, the Chief Executive Officer, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Purpose

Art. 1. This Resolution establishes inspection programs and criteria for the grant and renewal of the Certification of Good Manufacturing Practices for Medical Devices, in addition to the general provisions of administrative procedures when granting the Certification of Good Manufacturing Practices.

Section II

Scope

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

Art. 3. The manufacturing establishments of medical devices of risk classes III and IV that fall under one of the conditions below will be subject to the Certification of Good Manufacturing Practices for Medical Devices by Anvisa:

I - manufacturing establishments that produce a final product autonomously or for another company;

II - manufacturing establishments that perform the final release of the final product, associated with at least one production stage, excluding the design, distribution, sterilization, packaging and labeling stages;

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

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

§ 2 The manufacturing establishments of medical devices for in vitro diagnosis that perform the steps of impregnation, lamination or cutting of immunochromatography strips are subject to the 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, whether public or private, responsible for the design, manufacture, packaging and labeling of a product, with the intention of making it available for use under its name, whether these operations area 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;
IV - final product: the product subject to regularization that is fit for use or functionally complete, whether or not it is packaged, labeled or sterilized;
V - finished product: a product that has gone through all stages of production, including labeling, final packaging and sterilization (when applicable);
VI - inspection report: report describing the company's status regarding compliance with good manufacturing practices, in accordance with the standards referenced in the scope of the report;
VII - manufacturing unit: place where one or more manufacturing steps take place, which may be the premises of the legal manufacturer, of a contracted manufacturer or of the original product manufacturer.

CHAPTER II

APPLICATION DOCUMENTS

Art. 5 The cases to obtain a grant of 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 filled out;
II - general production flowchart related to the manufactured products, identifying which steps are performed in the establishment that is under certification;
III - layout of the establishment under certification, including the floor plan of the manufacturing establishment;
IV - list of all products subject to sanitary regularization in Brazil manufactured in the manufacturing establishment under certification, containing technical name, line (equipment, materials or medical devices for in vitro diagnosis) and respective risk class, which are or will be marketed in Brazil with the respective trade name;
V - statement indicating whether the products that are or will be marketed in Brazil are legalized in the country of origin and in countries that are part of MERCOSUR and IMDRF;
VI - list of all inspections or regulatory audits carried out at the establishment under certification in the last three (3) years, indicating the period of each inspection or audit; name of the authority or third party entity responsible for carrying it out; conclusion and details of any resulting regulatory action;
VII - copy of the inspection report used to prove compliance with good manufacturing practices before the health authority of the country of origin or document attesting compliance with 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 attesting that the company is part of 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 establishment under certification must be informed, even if it is not marketed in Brazil.
§ 2 For national manufacturers, only items I to IV apply, with the inspection reports being forwarded by state or municipal health authorities through a specific system, these reports may be replaced by proof that the manufacturing establishment is part of a specific audit program recognized by Anvisa.

§ 3 For manufacturers located in Mercosur member countries, only items I to V apply, with the inspection reports being forwarded by local health authorities, these reports may be replaced by proof that the factory is part of a specific audit program recognized by Anvisa.
§ 4 For manufacturers that are part of a specific audit program recognized by Anvisa, only items I to VI apply, and the audit reports must be made provided by the respective Auditing Entity.
§ 5 The procedures for recognition of the Auditing Entity are established in Resolution - RE No. 392, February 20, 2018.
Art. 6 The processes for renewing the Certification of Good Manufacturing Practices referred to in this Resolution must include all the documents listed in art. 5, with the exception of documents II, III, IV and V, which should only be included in the event that there are alterations in their contents.
Art. 7 The manufacturing establishment that is under certification may directly forward the documents referred to in items III to VIII of art. 5 to Anvisa, provided that these documents are duly identified and amend the corresponding case.
Sole paragraph. The deadline for submitting the documents mentioned in the head provision is thirty (30) days after the date of submission of the certification application.
CHAPTER III
GRANT OF GOOD MANUFACTURING PRACTICES CERTIFICATES - GENERAL PROVISIONS
Art. 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:
VIII - 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 ENTITIES within the scope of a specific audit program recognized by Anvisa;
IX - upon evaluation of the documents listed in art. 5 of this Resolution and after a risk analysis that justifies the issuance of the Good Manufacturing Practices Certificate;
X - upon evaluation of the inspection report issued by Anvisa as a result of the on-site inspection, motivated by 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 established in item I of art. 8, the audit reports must have been issued in the three (3) years prior to the date of the protocol, covering the risk classes and production lines pertaining to the certification request and leading to the conclusion that the establishment complies with good manufacturing practices.
§ 1 In case there are non-conformities listed in the audit reports, the action plans must be forwarded to Anvisa by the respective Auditing Entity.
§ 2 If the non-conformities presented in the report are pending, the applicant will receive a request and, once the applicant does not comply with the presentation of the listed items, their application shall be rejected.
Art. 10. The granting and renewal of certification by the mechanism established in item II of art. 8 will be carried out through a risk analysis tool published on the Anvisa Portal, considering the result of the evaluation of the documents listed in art. 5, the complexity of the manufacturing establishment, the technologies involved, the intrinsic risk of the products and the indicated use, among other characteristics.

§1 In the event that non-conformities are listed in the inspection or audit reports, action plans or proof of completion of corrective actions must be submitted, analyzed and deemed satisfactory by the issuer.
§2 If the non-conformities presented in the report are pending, the applicant will receive a request and, once the applicant does not comply with the presentation of the listed items, their application shall be rejected.
Art. 11. The granting and renewal of certification by the mechanism established in item III of art. 8 will result from the elimination of the possibilities established in items I and II of art. 8.
CHAPTER IV
INSPECTION PROGRAMS
Art. 12. Anvisa's verification compliance with Good Manufacturing Practices for Medical Devices may take place through specific inspection programs.
§1 The programs mentioned in the head provision of this article refer to a set of actions carried out with the purpose of inspection in manufacturing establishments of products registered with Anvisa.
§2 The programs will take place regardless of the certification processes.
§3 The programs will 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, and the historical data regarding the inspection, monitoring, and registration of the products.
§4 The inspection programs may be extended to national and international manufacturers and to those located in other Mercosur member countries.
§5 The programs will be planned considering the operational capacity of the Agency for carrying out inspections and will be evaluated, reviewed and published annually.
§6 The audit reports issued under the Medical Devices Single Audit Program (MDSAP) will also be used to verify compliance with Good Manufacturing Practices through the programs mentioned in this chapter.
CHAPTER V
TEMPORARY AND FINAL PROVISIONS
Art. 13. For all purposes, Anvisa considers reports issued by Auditing Entities through a specific audit program as evidence of compliance with good manufacturing practices and of the effects resulting from said compliance.
Art. 14. The certification issued based on the documentation established in §§ 1 and 2 of art. 9 does not exempt the company from receiving the on-site inspection by Anvisa, at any time, even during the validity term of the Certificate of Good Manufacturing Practices granted.
Sole paragraph. Should the establishment present an obstacle to receiving the on-site inspection from Anvisa, including requests to change the date unilaterally motivated by the establishment and not accepted by Anvisa, this will lead to the cancellation of the Good Manufacturing Practices Certificate.
Art. 15. A maximum period of 180 (one hundred and eighty) days is established for the application for the Good Manufacturing Practices Certificate for new manufacturing establishments covered by art. 3 of this resolution.
Art. 16. The Resolution of the Collegiate Board of Directors - RDC No. 183, October 17, 2017, published in the Federal Official Gazette No. 201, October 19, 2017, Section 1, p. 27, is hereby revoked.

Art. 17. This Resolution shall come into effect on June 1, 2022.