COLLEGIATE BOARD RESOLUTION – RDC NO. 183 OF 17 October 2017

Provides for inspection programs and administrative procedures to grant of Good Manufacturing Practices Certificate to manufacturers of Medical Devices located outside the Brazilian territory and Mercosur.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, combined with Article 7, items III and IV of Law no. 9782 dated 26 January 1999, and considering the provisions of item V, and Paragraphs 1 and 3 of Article 53 of the Internal Regulation approved by Annex I of Collegiate Board Resolution – RDC no. 61 of 3 February 2016, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 10 October 2017, and I, the Director-President, determine its publication:

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Article 1 This Resolution provides for inspection programs and establishes procedures to grant of Good Manufacturing Practices Certificate to manufacturers of Medical Devices located outside the Brazilian territory and Mercosur, as a complement to the provisions of Collegiate Board Resolution – RDC no. 39 of 14 August 2013.

Section II

Scope

Article 2 This Resolution applies to the grant of Medical Devices Good Manufacturing Practices Certificate to manufacturers located outside the Brazilian territory and Mercosur.

Sole paragraph. In order to assess compliance with the Good Manufacturing Practices by means of inspection programs, the guidelines established by this Resolution may extend to Brazilian manufacturers, as well as the manufacturers located in the other Mercosur countries.

Section III

Definitions

Article 3 For the purposes of this Resolution, the following definitions are adopted:

I – finished device: the product, being one, a family, a system, or a set of products, which is ready for use or functionally complete, whether it is packed, labeled, or sterilized, or not;

II – manufacturing site: the establishment where product manufacture or manufacturing stage occurs, and it may be the legal manufacturer, contracted manufacturer, or the Original Equipment Manufacturer – OEM.

CHAPTER II

PETITION DOCUMENTS

Article 4 All Good Manufacturing Practices Certification processes provided in this Resolution shall contain the following documents:

I – duly completed specific petition form for the Certification of Medical Devices Good Manufacturing Practices in other countries;

II – proof of payment, or exemption, of the *Taxa de Fiscalização de Vigilância Sanitária* – TFVS (Health Surveillance Inspection Fee), using a specific *Guia de Recolhimento da União* – GRU (official federal payment document);

III – quality manual of the manufacturing site undergoing the certification process;

IV – list of all products being manufactured by the manufacturing site undergoing the certification process, with an indication of the products that are or will be exported to Brazil;

V – general production flowchart of the products manufacturing processes, with the identification of which stages are performed at the manufacturing site undergoing the certification process;

VI – layout of the manufacturing site undergoing the certification process, including plant floor plans;

VII – copy of a valid conformity certificate (in the case of electromedical equipment), issued by the certifying body, when applicable;

VIII – list of all inspections or regulatory audits of the manufacturing site undergoing the certification process for the last 3 (three) years, with an indication of the period of each inspection or audit; name of the health authority or third party auditing organization responsible for its execution; conclusion and details of any consequent regulatory action;

IX – statement indicating in which countries the products that are or will be exported to Brazil are authorized, with the respective authorization documents;

X – copy of the latest inspection or audit report issued by the health authority from the country of origin or by a third party auditing organization recognized by the health authority;

XI – copy of the latest inspection or audit report issued by the health authority in an International Medical Device Regulators Forum (IMDRF) member country or by a third party auditing organization recognized by the health authority, when applicable; and

XII – copy of the latest audit report issued by a third party auditing organization recognized by Anvisa, when applicable.

Sole paragraph. The document protocol shall comply with the provisions in RDC no. 25, of 16 June 2011, and its updates.

Article 5 The manufacturing site undergoing the certification process may send the documents referred to in items VIII to XII of Article 4 directly to Anvisa, as long as the documents are duly identified and in addition to the related dossier.

Sole paragraph. The manufacturing site shall register the documents referred to in the caption of this article in up to 30 (thirty) days after the certification petition is registered.

CHAPTER III

MANUFACTURING SITES SUBJECT TO GOOD MANUFACTURING PRACTICES CERTIFICATION

Article 6 The following manufacturing sites are subject to Good Manufacturing Practices Certification for the purposes of authorization, authorization renewal, or change (inclusion or alteration) of medical devices manufacturer at Anvisa:

I – Manufacturing site that makes a finished device in its name or for another company;

II – Manufacturing site that is responsible for releasing the finished device, related to at least one production stage, except for designing, distribution, sterilization, packing, and labeling stages; and

III – Manufacturing site of Software as a Medical Device – SaMD.

Sole paragraph. Anvisa shall not issue a Good Manufacturing Practices Certificate to manufacturing sites not provided for in this article.

CHAPTER IV

INSPECTION PROGRAMS

Article 7 Anvisa shall assess the compliance with the Medical Devices Good Manufacturing Practices by the manufacturers located outside the Brazilian territory and Mercosur through specific inspection programs, as a priority.

Paragraph 1 The programs referred to in the caption of this article relate to a set of actions carried out for the purposes of inspection in manufacturing sites of products authorized by Anvisa.

Paragraph 2 The programs shall occur regardless of certification processes.

Paragraph 3 The programs shall be defined according to a health risk assessment considering the intrinsic risk of products, the complexity of manufacturing processes, technologies involved, and background data of inspection, monitoring, and authorization of products.

Paragraph 4 The inspection programs may be extensive to Brazilian manufacturers and those located in the other Mercosur member countries.

Paragraph 5 The programs shall be planned considering the Agency's operational capacity to carry out inspections, as well as assessed, reviewed, and published yearly.

Paragraph 6 The audit reports issued within the framework of the Medical Device Single Audit Program (MDSAP) shall also be used to assess the compliance with the Good Manufacturing Practices through the programs referred to in this chapter.

CHAPTER V

GRANT OF GOOD MANUFACTURING PRACTICES CERTIFICATES

Section I

General Provisions

Article 8 The grant of Good Manufacturing Practices Certificate of Medical Devices of risk classes III and IV may occur through one of the following, after document assessment:

I – on presentation of a valid audit report, issued by a third party auditing organization, in accordance with specific programs, both recognized by Anvisa;

II – using confidential information on inspections, received under Agreements or Covenants with health authorities of other countries;

III – by assessing inspection or audit report issued by the health authority of an IMDRF member country, or by a third party auditing organization recognized by the health authority;

IV – by assessing an audit report issued by a third party auditing organization recognized by Anvisa;

V – by making a risk analysis to assess the need for *in loco* inspection before granting the Good Manufacturing Practices Certificate, in the case of petitions not referred to or which do not comply with the requirements established for items I to IV above.

Section II

On the grant of the Good Manufacturing Practices Certificate on presentation of a valid audit report issued by a third party auditing organization, in accordance with specific programs, both recognized by Anvisa

Article 9 The Good Manufacturing Practices Certificate shall be granted to the manufacturers participating in the Medical Device Single Audit Program (MDSAP), after an assessment of the audit report presented in accordance with the guidelines established by the Program.

Section III

On the grant of the Good Manufacturing Practices Certificate using confidential information

Article 10 Anvisa may grant the Good Manufacturing Practices Certificate using confidential information on inspections, received under Agreements or Covenants with health authorities of other countries, after mutual recognition.

Sole paragraph. The guidelines and requirements to grant the Good Manufacturing Practices Certificate based on the provisions in the caption of this article shall be established under each Agreement or Covenant.

Section IV

On the grant of the Good Manufacturing Practices Certificate by assessing reports issued by the health authority of an IMDRF member country, by a third party auditing organization recognized by the health authority, or by a third party auditing organization recognized by Anvisa

Article 11 Anvisa may grant the Good Manufacturing Practices Certificate in the hypotheses of items III and IV of Article 8 under the following conditions:

I – by assessing the inspection or audit report presented in accordance with item XI of Article 4; or

II – by assessing the inspection or audit report presented in accordance with item XII of Article 4.

Paragraph 1 The inspection or audit report referred to in items I and II of this article shall comply with the guidelines of the document IMDRF/MDSAP WG/N24 FINAL: 2015 - *Medical Device Regulatory Audit Reports* and its updates.

Paragraph 2 The inspection or audit report shall have been issued in up to 2 (two) years prior to the date of protocol, include risk classes and production lines that are subject to the certification petition, and allow for the conclusion that the manufacturing site complies with the good manufacturing practices.

Section V

On the grant of the Good Manufacturing Practices Certificate for cases not referred to in the previous sections above

Article 12 In the occurrence of petitions not referred to, or which do not comply with the requirements in Sections II, III, or IV of this Chapter, Anvisa shall make a risk

analysis to assess the need for *in loco* inspection before granting the Good Manufacturing Practices Certificate.

Paragraph 1 The risk analysis shall be carried out based on a risk matrix previously defined by Anvisa, which considers the result of document assessment referred to in Article 4, the complexity of the manufacturing site, technologies involved, the intrinsic risk of products, and indication of use.

Paragraph 2 In the occurance of manufacturing sites previously certified by Anvisa, the risk analysis referred to in the caption of this article shall also consider:

I – the history of compliance with the Good Manufacturing Practices by the manufacturing site undergoing the certification process, obtained by Anvisa from its database;

II – the history of proven deviations, technical complaints, adverse events, field action notifications, and/ or health infractions proven by competent authorities, obtained by Anvisa from its database;

III – time period since the last inspection; and

IV – status of product authorization.

Paragraph 3 The risk analysis may also indicate an *in loco* inspection of reduced scope.

CHAPTER VI

TRANSITIONAL PROVISIONS

Article 13 There shall be a transition period between the current form of action and the one provided for in this Resolution to assess the compliance with the Medical Devices Good Manufacturing Practices by the manufacturers located outside the Brazilian territory and Mercosur.

Article 14 The companies that did not have an international inspection scheduled or carried out by Anvisa shall present:

I – the documents referred to in Article 4 that have not been presented yet;

II – formal statement if the company is or is not still interested in being granted the Good Manufacturing Practices Certificate.

Paragraph 1 The document presentation referred to in items I and II of this article shall occur as an addition to the initial certification dossiers, in up to 60 (sixty) days from the date this Resolution is published.

Paragraph 2 The certification petitions not including the documents referred to in items I and II of this article, within the period of time established, are subject to rejection.

Paragraph 3 In the cases where companies present a formal statement of withdrawal of petitions not assessed yet by Anvisa, the matters related to reimbursement of fees shall be dealt with directly at Anvisa's *Gerência de Gestão de Arrecadação* – Gegar (Collection Management Office).

Article 15 Anvisa will take exceptional and transitional measures aiming at granting Medical Devices Good Manufacturing Practices Certificates to manufacturing sites located in other countries, the petitions of which (subject code 8331 and 8079) were registered until the date this Resolution is published.

Paragraph 1 For petitions of manufacturers that currently take part in the Canadian Medical Devices Conformity Assessment System – CMDCAS, and will move to the Medical Device Single Audit Program (MDSAP), a valid proof of participation in the CMDCAS program shall be presented within 60 (sixty) days in order to show the company is compliant with its requirements.

Paragraph 2 For petitions of manufacturers that have been audited by a third party auditing organizations recognized by Anvisa, an audit certificate or report stating the compliance with the Good Manufacturing Practices, issued by the auditing organization, shall also be presented within 60 (sixty) days, and include in its scope the manufacturing stages, risk classes, and the production lines of the products in the certification petition.

Article 16 The petitions referred to in Articles 14 and 15 shall be analyzed after 60 (sixty) days from the date this Resolution is published.

Sole paragraph. Analysis of the dossiers shall observe the initial chronological order of petition entry.

Article 17 Anvisa shall assess the compliance with the requirements in Article 4, 14, and 15, and the grant of Good Manufacturing Practices Certificates to petitions registered by the date this Resolution is published may occur, on an exceptional basis, as follows:

I – on presenting a document stating that the manufacturing site undergoing the certification process participates in the CMDCAS program and also meets its requirements;

II – on presenting an audit certificate or report issued by an auditing organization recognized by Anvisa, which states the compliance with the Good Manufacturing Practices by the manufacturing stages, risk classes, and production lines undergoing the certification petition; or

III – on carrying out a risk analysis to assess the need of an *in loco* inspection before granting the Good Manufacturing Practices Certificate, in the case of petitions not referred to, or not meeting the requirements established in the previous items.

Article 18 If the third party auditing organization working within the CMDCAS program is not recognized by the Medical Device Single Audit Program (MDSAP) in the future, Anvisa may reassess the grant of certificates cerissued in accordance with the provisions in Article 17.

Article 19 In the period of 60 (sixty) days established for the addition of documents to the initial certification dossiers, the international inspection schedule shall be maintained, based on the criteria established before this Resolution is published.

Sole paragraph. Requests to alter inspection dates agreed upon by the parties and already approved by Anvisa's competent office shall not be approved, and the refusal to meet the date initially scheduled shall result in the petition's rejection.

Article 20 Anvisa's Health Inspection Office (GGFIS) shall notify the Medical Devices Technology Office (GGTPS) about all rejections and requests of withdrawal from the Good Manufacturing Practices Certification occurring during the transition period referred to in this chapter.

CHAPTER VII

FINAL PROVISIONS

Article 21 The certification petitions not containing the documents required at the moment of presentation, or petitions with unsatisfactory result of the technical analysis, are subject to rejection.

Article 22 The certification issued based on the documents provided for in articles 9, 10, 11, and 12 does not exempt the company from receiving an *in loco* inspection by Anvisa, at any time, even during the validity of the Good Manufacturing Practices Certificate of which was granted, and the company may not refuse to receive the inspection.

Paragraph 1 The refusal to receive the inspection referred to in the caption of this article will cause the precautionary suspension of the certificate until the inspection is concluded and its report is issued, stating the compliance with the Good Manufacturing Practices is satisfactory.

Paragraph 2 The refusal referred to in the caption of this article will also cause the opening of health administrative proceedings against the company that requested the certificate; import and commercialization may be suspended, and the products involved may be deemed subject to withdrawal.

Article 23 The refusal to receive inspections planned under the programs, regardless of the company being certified or not by Anvisa, will cause the opening of health administrative proceedings against the authorization holder in Brazil; import and commercialization may be suspended, and the products involved may be deemed subject to withdrawal.

Article 24 This Resolution revokes Article 2 of RDC no. 179 of 27 September 2017, published on the Federal Official Gazette of 2 October 2017.

Article 25 This Resolution enters into force on the date of its publication.

JARBAS BARBOSA DA SILVA JR.