Establishes the scope of application of the provisions of GMP of medical devices and in-vitro diagnostic products to importers, distributors and storage companies, and makes other considerations.

The Collegiate Board of Directors of the Brazilian National Health Surveillance Agency (ANVISA), in the exercise of the powers vested by Article 15, subsections III and IV, of Law 9,782, of January 26th, 1999, in view of the provisions of Article 54, paragraphs 1 and 3, of the Internal Statute approved under the terms of Annex I of Anvisa Ordinance no. 354, of August 11th, 2006, republished on the Brazilian Official Gazette of August 21st, 2006, and its updates, in view of the provisions of Article 2, subsection III, of Article 7, subsections III and IV, of Law no. 9,782/1999, and the Program for Improvement of the Agency's Regulatory Process, created by Ordinance no. 422, April 16th, 2008, as well as of RDC 16, of March 28th, 2013, published on April 1st, 2013, which makes provisions on the technical regulation of Good Manufacturing Practices of medical devices and in-vitro diagnostic products, in meeting held on December 19th, 2013, hereby resolves:

Article 1. This Normative Instruction hereby establishes the requirements of the technical regulation of Good Manufacturing Practices of medical devices and in-vitro diagnostic products applicable to importers, distributors and storage companies.

Sole Paragraph. Manufacturers shall fully comply with the requirements of the technical regulation of Good Manufacturing Practices of medical devices and in-vitro diagnostic products.

Article 2. Importers shall fully comply with the following provisions of RDC 16, of March 28th, 2013:

I - Item 1.1.2 of Chapter 1;

II - Chapter 2 – General Quality System Requirements;

III - Items 3.1 and 3.3 of Chapter 3 – Quality Documents and Records;

IV - Items 4.2.1.3, 4.2.1.4 and 4.2.1.5 of Chapter 4 – Design Control and Design Master Record (DMR);

V - Items 5.1.2, 5.1.3, 5.1.4, 5.2.2, 5.3 and 5.4 of Chapter 5 – Process and Production Controls;
VI - Chapter 6 – Handling, Storage, Shipping and Traceability, except item 6.5.3;

VII - Chapter 7 – Corrective and Preventive Actions;

VIII - Chapter 8 – Installation and Technical Assistance;

IX - Chapter 9 – Statistical Techniques.

Sole Paragraph. For the identification and traceability contained in item 6.4 and for the inspection of labels and instructions for use in item 5.2.2.3 thereof, importers may use a document of their own as a replacement to the device master record.

Article 3. Distributors shall fully comply with the following provisions of RDC 16, of March 28th, 2013:

I - Item 1.1.2 of Chapter 1;

II - Chapter 2 – General Quality System Requirements, except item 2.4;

III - Item 3.1 of Chapter 3 – Quality Documents and Records;

IV - Items 5.1.2, 5.1.3, 5.1.4, and 5.4 of Chapter 5 – Process and Production Controls;

V - Chapter 6 – Handling, Storage, Shipping and Traceability, except item 6.5.3;

VI - Chapter 7 – Corrective and Preventive Actions; and

VII - Chapter 8 – Installation and Technical Assistance.

Sole Paragraph. For the identification and traceability contained in item 6.4 thereof, distributors may use a document of their own as a replacement to the device master record.

Article 4. Storage companies shall fully comply with the following provisions of RDC 16, of March 28th, 2013:

I - Item 1.1.2 of Chapter 1;

II - Chapter 2 – General Quality System Requirements, except item 2.4;

III - Item 3.1 of Chapter 3 – Quality Documents and Records;

IV - Items 5.1.2, 5.1.3 and 5.1.4 of Chapter 5 – Process and Production Controls;

V - Chapter 6 – Handling, Storage, Shipping and Traceability, except item 6.5.3; and

VI - Chapter 7 – Corrective and Preventive Actions.

Sole Paragraph. For the identification and traceability contained in item 6.4 thereof, distributors may use a document of their own as a replacement to the device master record.
Article 5. Companies that conduct more than one activity shall comply with the specific requirements herein established for such activities.

Article 6. The documentation that evidences compliance with the requirements hereof shall be available whenever requested by health surveillance bodies.

Article 7. This Normative Instruction shall come into force on the date of its publication.

DIRCEU BRÁS APARECIDO BARBANO