Draft Resolution No 10 of 27 January 2010.

BRAZILIAN OFFICIAL GAZETTE (DIÁRIO OFICIAL DA UNIÃO – DOU) OF 1 FEBRUARY 2010

The Collegiate Directorate of the Agência Nacional de Vigilância Sanitária – ANVISA (Brazilian Health Surveillance Agency), pursuant to the powers conferred on it by Article 11(IV) and Article 35 of the ANVISA Regulation approved by Decree No 3029 of 16 April 1999, and having regard to the provisions of Item V and points 1 and 3 of Article 54 of the Internal Regulations approved in accordance with Annex I of ANVISA Administrative Ruling No 354 of 11 August 2006, republished in the DOU of 21 August 2006, at a meeting held on 18 January 2010,

hereby adopts the following Draft Resolution, and I, the Director-President, order its publication:

Article 1 – A period of sixty days from the date of publication of this Draft Resolution is hereby declared open for submitting criticisms and suggestions on the proposed Technical Regulation laying down minimum identity and quality requirements for sterile hypodermic needles for single use, as detailed in the Annex.

Article 2 – This full proposal will be available during the consultation period at www.anvisa.gov.br and any suggestions should be sent in writing to: Agência Nacional de Vigilância Sanitária, Gerência Geral de Tecnologia de Produtos para Saúde, S.I.A., Trecho 5, Lote Especial 57, Brasília – DF – 71.205-050, Brazil, by fax (061) 3462-6644 or by email to tecnologia.produtos@anvisa.gov.br.

Article 3 – At the end of the period stipulated in Article 1, the ANVISA will make contact with the interested parties and others who have expressed interest in order that they may appoint representatives for subsequent discussions with a view to consolidating the final text.

DIRCEU RAPOSO DE MELLO

ANNEX

COLLEGIATE DIRECTORATE RESOLUTION (RDC) NO … OF … 2009

Laying down minimum identity and quality requirements for sterile hypodermic needles for single use.

The Collegiate Directorate of the National Health Surveillance Agency, pursuant to the powers conferred on it by Article 11(IV) and Article 35 of the ANVISA Regulation approved by Decree No 3029 of 16 April 1999, and having regard to the provisions of Item V and points 1 and 3 of Article 54 of the Internal Regulations approved in accordance with Annex I of ANVISA Administrative Ruling No 354 of 11 August 2006, republished in the DOU of 21 August 2006, at a meeting held on [date], and
Whereas the Ministry for Health established a quality assurance system for related products by adopting the Brazilian Conformity Assessment System with a view to assuring the safety and quality of such materials;

Having regard to the notifications received in relation to problems with the quality of sterile hypodermic needles for single use;

Having regard to the need to establish minimum requirements for infusion equipment in order to guarantee its quality, safety and effectiveness, and to protect consumers; hereby decides

Article 1 – To approve the Technical Regulation laying down minimum identity and quality requirements for sterile hypodermic needles for single use, as specified in the Annex.

Article 2 – Sterile hypodermic needles for single use must also meet the conformity certification requirements laid down by the Brazilian Conformity Assessment System.

Sole paragraph: Brazilian manufacturers and importers may choose certification by system assessment and product testing or by assessment on a batch-by-batch basis.

Article 3 – Companies have 180 days in which to adjust to the provisions laid down in this Resolution.

Article 4 – This Resolution shall enter into force on the date of its publication.

DIRCEU RAPOSO DE MELLO

ANEXO

TECHNICAL REGULATION LAYING DOWN MINIMUM IDENTITY AND QUALITY REQUIREMENTS FOR STERILE HYPODERMIC NEEDLES FOR SINGLE USE

1. OBJECTIVE: To lay down minimum identity and quality requirements for sterile hypodermic needles for single use.

2. DEFINITIONS: The following definitions shall apply for the purposes of this Regulation:

2.1 Cannula – Stainless steel tube of specified dimensions, with a bevel at one end.

2.2 Lock – Link made of plastic, aluminium alloy or other alloy, enabling the needle to be coupled to the syringe or any male Luer connector.

2.3 Needle – Cannula firmly fitted into the lock.

2.4 Protector – Accessory adaptable to the lock, intended to protect the cannula.

2.5 Bevel – sharp, cutting part of the cannula.
3. **DESIGNATION.** The designation of the needle shall be: "Single-use sterile hypodermic needle".

4. **REFERENCES**


4.2 **BRAZIL,** Interministerial Order MS/MIDC No 692 of 8 April 2009, defining the implementation of technical cooperation for the quality and safety assurance of medical devices subject to the health inspection arrangements, as laid down in the Technical Cooperation Agreement between the Health Ministry (MS) and the Ministry for Development, Industry and External Trade (MDIC).


4.5 **Brazil,** ANVISA RDC No 156 of 11 August 2006, on the registration, labelling and re-processing of medical products and other provisions.

4.6 **BRASIL ANVISA RDC No 207 of 17 November 2006,** amending Resolution No 185, concerning the registration, amendment, renewal and cancellation of the registration of medical products with the ANVISA, *DOU* Brasília, Government, of 6 November 2001.

4.7 **Brazil,** ANVISA RDC No 59 of 27 June 2000. Technical Resolution laying down essential safety and effectiveness requirements applicable to health products, compliance with the requirements of "Good Practice in the Manufacture of Medical Products" *DOU* Brasília, Government, of 29 June 2000.


4.9 **Brazil,** ABNT, NBR No 9259:1997, approving the Brazilian Standard for sterile hypodermic needles for single use.

4.10 **Brazil,** ABNT, NBR No 9626:2003, approving the Brazilian Standard for stainless steel tubes for needles for the manufacture of medical devices.

4.11 **Brazil,** ABNT, NBR No 5601:1981, approving the Brazilian Standard for stainless steel – classification by chemical composition - Standardisation.

4.12 **Brazil,** ABNT, NBR No 594-1:2003, Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment, Part 1 – General Requirements.
4.13 Brazil, ABNT, NBR No 594-2:2003, Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment, Part 2 – Fixed Assembly.


5. GENERAL PRINCIPLES

5.1. Manufacturers of sterile hypodermic needles for single use must observe the *Boas Práticas de Fabricação* – BPF (Good Manufacturing Practices).

5.2. Materials used in the manufacture of sterile hypodermic needles for single use must be compatible with fluids to be injected and must not alter their physical or chemical properties.

5.3. Sterile hypodermic needles for single use must be free of contaminants that may pose a risk to human health.

5.4. Manufacturers of sterile hypodermic needles for single use must demonstrate that the needles are compatible with syringes.

5.5. Sterile hypodermic needles for single use may be externally lubricated.

5.6. Cannulas of sterile hypodermic needles for single use must be straight and tubular, with a circular cross-section, and with an angular displacement of no more than three degrees. The outer surface must be clean, entirely smooth and free of protuberances.

5.7. The tubes of sterile hypodermic needles for single use must be made from stainless steel for the manufacture of medical devices, as defined in the applicable Standards.

6. MINIMUM REQUIREMENTS:

6.1. Sterile hypodermic needles for single use must meet the following requirements:

6.1.1. Physical tests:

6.1.1.1. Materials for using the cannula and the lock;
6.1.1.2. Cleanliness conditions;
6.1.1.3. Presence of lubricant;
6.1.1.4. Strength of the protector;
6.1.1.5. Rigidity;
6.1.1.6. Sealing of the junction between the cannula and the lock;
6.1.1.7. Safety of the junction between the cannula and the lock;
6.1.1.8. Breaking strength;
6.1.2. Chemical tests: 6.1.2.1. Corrosion resistance;

6.1.3. Biological tests:

6.1.3.1. Toxicity;
6.1.3.2. Sterility;
6.1.3.3. Pyrogenicity.

6.2. Tests, procedures and methods of analysis are those described in the Brazilian Standards applicable to the product.

7. PACKAGING AND LABELLING

7.1 – Sterile hypodermic needles for single use must be placed in plastic protectors and packaged individually.

7.2 – Packaging must be such that single-use sterile hypodermic syringes for manual use or use with a syringe pump remain intact, especially in order to maintain the sterility of the content.

7.3 – The individual packaging of sterile hypodermic needles for single use must show clear evidence, when open, that it has indeed been opened and that it cannot be resealed after opening.

7.4 – The wording on labelling of sterile hypodermic needles for single use must comply with the requirements laid down in the corresponding Brazilian Standards and with the health legislation applicable to medical devices.

8. SAMPLING

8.1 – The sampling plans, special inspection levels and acceptable quality levels applicable to single-use sterile hypodermic syringes for manual use or use with a syringe pump must be those laid down in the Brazilian Standards. In the event of suspicion or notification of deficiencies in one or more batches, the ANVISA may demand more stringent inspection levels.

9. PACKAGING

9.1 – Sterile hypodermic needles for single use must be packaged in such a way that the product is protected and remains intact from its manufacture to its end use.

10. STORAGE

10.1 – Sterile hypodermic needles for single use must be stored and transported under conditions that ensure that it is unaffected, in particular, by heat, humidity and light.