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Ministry of Health of
the National Health Surveillance Agency

RESOLUTION - RDC NO. 27, OF JUNE 21, 2011

Provides for the procedures for compulsory certification of equipment under the Sanitary Surveillance regime.

The Collegiate Board of Directors of the National Health Surveillance Agency, in the exercise of the powers conferred on it by item IV of article 11 of the Regulation approved by Decree No. 3,029, of April 16, 1999, and in view of the provisions of item II and paragraphs 1 and 3 of article 54 of the Internal Regulations approved pursuant to Annex I of Ordinance No. 354 of ANVISA, of August 11, 2006, republished in the Official Gazette of August 21, 2006, in a meeting held on June 7, 2 0 11 ,

Adopts the following Resolution of the Collegiate Board of Directors and I, Chief Executive Officer, determine its publication:

Art. 1 The Technical Regulation that establishes the procedures for compulsory certification of equipment under the Sanitary Surveillance regime is hereby approved, under the terms of this Resolution.

Art. 2 - The equipment under the Sanitary Surveillance regime must prove compliance with ANVISA RDC Resolution No. 56, of April 6, 2001, which "Establishes the Essential Safety and Efficacy Requirements Applicable to Health Products", by means of conformity certification within the scope of the Brazilian Conformity Assessment System (SBAC).

Paragraph 1 - In order to comply with the provisions of the caput of this article, the prescriptions contained in technical standards indicated by means of ANVISA IN Normative Instruction No. 3, of June 21, 2011, or its updates, shall be taken as a basis.

Paragraph 2 - The following shall be considered equipment under the Sanitary Surveillance regime, including its parts and accessories:

I - equipment for medical, dental, laboratory or physiotherapeutic purposes, used directly or indirectly for diagnosis, treatment, rehabilitation and monitoring of human beings; and

II - equipment for the purpose of beautification and aesthetics.

Paragraph 3 - The certification referred to in the caput of this article shall not constitute a single procedure for proving the safety and efficacy of the products, and complementary studies and analyses may be requested in accordance with the provisions of ANVISA RDC Resolution No. 56/2001, which "Establishes the Essential Requirements of Safety and Efficacy Applicable to Health Products".

Article 3 - The supplier of equipment under the Sanitary Surveillance regime must present, for the purpose of granting, changing or revalidating the registration or registration of its product with ANVISA, a certified copy of the certificate of conformity issued by an accredited body within the scope of the SBAC.

Paragraph 1 - The company requesting registration or registration with ANVISA of imported equipment under the Sanitary Surveillance regime is exempt from presenting the free trade certificate of the product or registration certificate of its country of origin, provided for in ANVISA RDC Resolution No. 185, of October 22, 2011, which "Deals with the Registration, Alteration, Revalidation and Cancellation of the Registration of Medical Products at the National Health Surveillance Agency - ANVISA", when presenting the certificate of conformity of the equipment issued under the terms of this Resolution.

Paragraph 2 - The changes in registration or registration indicated in the caput of this article are those that have an impact on the normative requirements used in the equipment certification process.

Paragraph 3 - It shall be incumbent upon the body that has granted the certificate of conformity to the product to assess the impact of the change in the certificate granted.

Art. 4 - If it is not possible to issue the certificate of conformity within the scope of the SBAC, the registration or registration of the product may be granted, changed or revalidated without the presentation of such certificate.

Paragraph 1 - The company must prove the situation indicated in the caput of this article by means of a declaration from a Product Certification Body, accredited by the National Institute of Metrology, Standardization and Industrial Quality (INMETRO), informing about the impossibility of certification, containing the appropriate justifications.

Paragraph 2 - The holder of registrations or registrations granted under the conditions described in the caput of this article shall have a period of 180 (one hundred and eighty) days to present the Certificate of Conformity referred to in article 3, counted from the reestablishment of the conditions of capacity for certification within the scope of the SBAC.

Paragraph 3 - Failure to present the certificate within the period established in the previous paragraph shall result in the initiation of the procedures for suspension and subsequent cancellation of the registration or registration of the equipment.

Paragraph 4 - In the event that the impossibility of certification is due to transitory and partial problems, for the granting, alteration or revalidation of registration or registration of the equipment, a consolidated report must be submitted, according to the provisions contained in the Annex to this Technical Regulation, issued by a Product Certification Body (OCP), based on test reports issued by testing laboratories.

Paragraph 5 - The testing laboratories and the OCP indicated in the previous paragraph must be those accredited within the scope of the SBAC, and as many laboratories as necessary may be used so that the largest possible number of items of the technical standards are evaluated.

Paragraph 6 - The consolidated report issued referred to in paragraph 4 shall include the largest possible number of items of the technical standards applicable to the equipment, for which there are conditions of technological infrastructure for testing in Brazil.

Paragraph 7 - The tests referred to in paragraph 4 shall be based on the prescriptions contained in technical standards indicated in ANVISA IN Normative Instruction No. 3, of 2011, or its updates, which are applicable to the equipment.

Paragraph 8 - Only consolidated reports that indicate compliance with all items verified and written in Portuguese will be accepted.

Paragraph 9 - For equipment tested abroad, the test reports may be accepted for the purpose of preparing the consolidated report, provided that the following provisions are met:

I - have been issued by laboratories accredited by institutions that are proven to be signatories of the International Laboratory Accreditation Cooperation (ILAC); and

II - contemplate, at least, all the items of the standards tested for which there are conditions of technological infrastructure for testing in Brazil.

§ 10 Companies that choose to voluntarily submit the certificate of compliance, issued under the SBAC, based on a Memorandum of Understanding (MOU), will be exempt from submitting the consolidated report.

Art. 5 - The testing and certification process of equipment under the Sanitary Surveillance regime shall be subject to the prescriptions established in the Conformity Assessment Regulation of these products, approved by ANVISA within the scope of the SBAC.

Art. 6 It is essential to maintain the certificate of conformity, according to the technical standards indicated in ANVISA Normative Instruction IN No. 3, of 2011, or its updates, during the validity period of the product registration or registration.

Paragraph 1 - If the cancellation or expiration of the certificate of conformity occurs during the validity of the registration or registration of the product, the company shall have a period of ninety (90) days to present a new product certificate.

Paragraph 2 - The absence of the certificate of compliance for more than ninety (90) days will result in the initiation of procedures for suspension and subsequent cancellation of the registration or registration of the equipment.

Paragraph 3 - The period provided for in the previous paragraph shall not apply if the reason for the cancellation or suspension of the certificate of conformity arises from the finding of non-compliance with the technical standards, indicated in ANVISA Normative Instruction IN No. 3, of 2011, or its updates, and which are applicable to the equipment.

Art. 7 This Resolution enters into force on the date of its publication. Art. 8 ANVISA Resolution No. 32, of May 29, 2007, is hereby revoked.

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ANNEX

The consolidated report shall be issued on the letterhead of the product certification body, containing at least the following information:

1. Name and address of the OCP;
2. OCP identification mark;
3. OCP accreditation number under SBAC;
4. Name and business model of the equipment;
5. Company name and address of the manufacturer;
6. Corporate name and address of the report requester, at if it is different from that indicated in the previous item;
7. Description of the equipment, including its indication, purpose of use and the list of accessories and parts that have been tested together with the equipment;
8. Technical standards under which the test reports have been based, with an indication of which items of these standards could not be be verified;

9. Names of the testing laboratories used, accompanied the names of their respective accrediting bodies, and indication if they are proven to be signatories of the ILAC;
10. Results obtained in the tests for each item checked of the referenced technical standards, with an indication of whether the equipment tested is in accordance with or does not conform to the requirements of the item;
11. Indication of the items of the referenced technical standards that have not been verified;
12. Final conclusion, explaining whether there was a proven full compliance with the evaluated items of the indicated technical standards; and
13. Date, identification and signature of those responsible for the issuance of the report.

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