

BRAZILIAN NATIONAL HEALTH SURVEILLANCE AGENCY

COLLEGIATE BOARD OF DIRECTORS

RESOLUTION - RDC No. 27, OF JUNE 21ST 2011

Makes provisions on the procedures for the mandatory certification of equipment under the Health Surveillance system.

The Collegiate Board of Directors of the Brazilian National Health Surveillance Agency, in exercise of the powers attributed to it by Article 11, subsection IV, of the Regulation approved by Decree No. 3029, of April 16th, 1999, and in view of the provisions of Article 54, subsection II and § 1 and § 3, of the Internal Statute approved in accordance with Annex I of Anvisa Ordinance No. 354, of August 11th, 2006, republished on the Brazilian Official Gazette of August 21st, 2006, at a meeting held on June 7th, 2011, hereby adopts the following resolution and I, Director-President, determine its publication:

Article 1. The Technical Regulation that establishes the procedures for the compulsory certification of equipment under the Health Surveillance System is hereby adopted under the terms of this Resolution.

Article 2. The equipment subject to health surveillance shall prove compliance with Resolution RDC No. 56, of April 6th, 2001, which "establishes the essential safety and effectiveness requirements for healthcare products", by means of the certification of conformity within the scope of the Brazilian Compliance Assessment System (SBAC).

Paragraph 1. In order to comply with the provisions set forth in this article, the requirements contained in Anvisa Normative Instruction No. 3, of June 21st, 2011, or the amendments thereto, shall be taken into account.

Paragraph 2. The following shall be considered as equipment subject to the health surveillance system, including parts and accessories thereof:

I - equipment intended for medical, dental, laboratory and physiotherapeutic purposes, directly or indirectly used for diagnosis, treatment, rehabilitation and monitoring in humans; and

II - equipment intended for beautification and aesthetic purposes.

Paragraph 3. The certification referred to in the caput of this article shall not constitute a single procedure to evidence the safety and efficacy of the products, provided that complementary studies and analysis may be requested according to Resolution RDC No. 56/2001, which "establishes the essential safety and effectiveness requirements for

healthcare products."

Article 3. Suppliers of equipment subject to the Health Surveillance System shall submit, for the purposes of granting, changing or revalidating the *registro* or *cadastr*o of their products at ANVISA, a certified copy of the certificate of conformity issued by bodies accredited within the scope of SBAC.

Paragraph 1. Companies requesting for the *registro* or *cadastr*o at Anvisa of imported equipment subject to the Health Surveillance System are hereby exempt from submitting the Free Sale Certificate related to the product or the registration certificate of their country of origin, as set forth in Resolution RDC ANVISA No. 185, of October 22nd, 2011, which "addresses the *registro* of medical products at Anvisa, as well as its change, renewal and cancellation", when submitting the equipment's certificate of conformity issued under the terms of this Resolution.

Paragraph 2. Changes in the *registro* or *cadastr*o specified in the caput of this article are those that have an impact on the regulatory requirements used in the equipment certification process.

Paragraph 3. The body issuing the product's certificate of conformity shall assess the impact of such changes on the granted certificate.

Article 4. Should it not be possible to issue the certificate of conformity within the scope of SBAC, the *registro* or *cadastr*o of the product may be granted, changed or revalidated without the submission of such.

Paragraph 1. The company must prove the situation indicated in the caput of this article by means of a statement provided by a Product Certification Body, accredited by the National Institute of Metrology, Standardization and Industrial Quality (INMETRO), informing about the impossibility to issue such certification along with the due justifications.

Paragraph 2. The holder of *registros* or *cadastr*os granted under the conditions described in the caput of this article shall have 180 (one hundred and eighty) days to submit the Certificate of Conformity aforementioned in Article 3, as of the date the capacity conditions for the certification within the scope of SBAC are restored.

Paragraph 3. The failure to present the certificate within the period specified in the preceding paragraph shall imply in the beginning of the procedures for suspension and subsequent cancellation of the equipment *registro* or *cadastr*o.

Paragraph 4. Should the impossibility of certification result from partial transient problems, a consolidated report shall be submitted, for the concession, change or revalidation of the equipment *registro* or *cadastr*o, according to the provisions of the Annex of the herein

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 preceding paragraph shall be accredited within the scope of SBAC and as many laboratories as necessary may be used so that the largest possible number of items of technical standards is evaluated.

Paragraph 6. The consolidated report aforementioned in paragraph 4 shall comprise the largest possible number of items of technical standards applicable to the equipment for which there are technological infrastructure conditions for the tests to be performed in Brazil.

Paragraph 7. The tests referred to in paragraph 4 shall be based on the provisions contained in the technical standards specified at ANVISA'S Normative Instruction No. 3, of 2011, or amendments thereto, that are applicable to the equipment.

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

Paragraph 9. For equipment tested overseas, test reports may be accepted in order to prepare the consolidated report, provided that the following provisions are observed:

- I – such reports have been issued by laboratories accredited by institutions which are signatories of the International Laboratory Accreditation Cooperation (ILAC); and
- II - contemplate, at least, all items of the tested standards for which there are technological infrastructure conditions for the tests to be performed in Brazil.

Paragraph 10. Companies that voluntarily choose to submit the certificate of conformity issued within the scope of SBAC, based on the Memorandum of Understanding – MOU, shall be exempt from the submission of the consolidated report.

Article 5. The process to test and certify the equipment subject to the Health Surveillance System shall be subject to the requirements established in the Compliance Assessment Regulation of these products, approved by ANVISA within the scope of SBAC.

Article 6. The maintenance of the certificate of compliance shall be essential during the valid period of the *registro* or *cadastro*, according to the technical standards indicated in the Normative Instruction of ANVISA No. 3, of 2011, or amendments thereto.

Paragraph 1. If the cancellation or expiration of the certificate of conformity occurs during the valid period of the *registro* or *cadastro*, the company shall have 90 (ninety) days to submit a new product certificate.

Paragraph 2. The failure to submit a certificate of conformity for more than 90 (ninety) days shall imply in the beginning of procedures for the suspension and the subsequent cancellation of the equipment *registro* or *cadastro*.

Paragraph 3. The aforementioned term shall not apply if the reason for the cancellation or suspension of the certificate of conformity results from the verification of the non-

compliance with the technical standards indicated in the Normative Instruction of ANVISA No. 3, of 2011, or amendments thereto, and that are applicable to the equipment.

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

Article 8. ANVISA Resolution No. 32, of May 29th, 2007, is hereby revoked.

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ANNEX

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

1. Name and address of the OCP;
2. Identification mark of the OCP;
3. Accreditation number of the OCP within the scope of SBAC;
4. Commercial name and model of the equipment;
5. Company name and address of the manufacturer;
6. Company name and address of the applicant's report, in case it differs from the previous item;
7. Description of the equipment, including its indication, intended use and the list of accessories and parts that have been tested along with the equipment;
8. Technical standards on which the test reports were based, indicating which items of these standards could not be verified;
9. Name of the testing laboratories used, along with the names of their respective accrediting bodies and indication if these are truly signatories of the ILAC;
10. Results from the tests for each verified item of the technical standards in question, indicating if the tested equipment complies or not with the requirements of the item;
11. Indication of the items of the referred technical standards that have not been verified;
12. Final conclusion, stating if there was total compliance with the evaluated items of the technical standards, and
13. Date, signature and identification of those responsible for issuing the report.