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RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS – RDC No. 549, OF AUGUST 30, 2021

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

The Collegiate Board of the National Health Surveillance Agency, in the use of the powers conferred on it by articles 7, item III, and 15, items III and IV, of Law No. 9,782, of January 26, 1999, and considering the provisions of article 53, item VI and §§ 1 and 3, of the Internal Regulations, approved by the Resolution of the Collegiate Board of Directors - RDC No. 255, of December 10, 2018, resolves to adopt the following Resolution of the Board of Executive Officers, as resolved at a meeting held on August 30, 2021, and I, the Chief Executive Officer, determine its publication.

CHAPTER I
GENERAL PROVISIONS

Art.1 This Resolution establishes the procedures for compulsory certification of equipment under the Sanitary Surveillance regime.

Art. 2 The equipment under the Sanitary Surveillance regime must prove compliance with the Collegiate Board Resolution - RDC No. 546, of August 30, 2021, or another that may replace it, through compliance certification under the Brazilian System of Conformity Assessment (SBAC).

§ 1 - To comply with the provisions of the caput of this article, the prescriptions contained in technical standards indicated through ANVISA IN Normative Instruction No. 49, of November 22, 2019, or their updates, shall be taken as a basis.

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

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

2. - equipment for the purpose of beautification and aesthetics.

§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 the Collegiate Board Resolution - RDC No. 546, of August 30, 2021, or another that may replace it.

Art. 3 The supplier of equipment under the Sanitary Surveillance regime must present, for the purpose of granting, altering or revalidating the registration or registration of its product with ANVISA, a copy of the certificate of conformity issued by an accredited body under the Brazilian System of Conformity Assessment (SBAC).

§1 - The company requesting the registration or notification in ANVISA of equipment under the imported Sanitary Surveillance regime is exempt from presenting the certificate of free trade of the product or certificate of registration of its country of origin, provided for in the Resolution of the Collegiate Board of Directors - RDC No. 185, of October 22, 2001, or another that may replace it, when submitting the certificate of conformity of the equipment issued pursuant to this Resolution.

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

§ 3 - It will be up to the body that has granted the certificate of conformity to the product to evaluate the impact of the change in said document.

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Art. 4 If it is not possible to issue the certificate of conformity under the SBAC, the registration or notification of the product may be granted, amended or revalidated without the presentation of such certificate.

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

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

§ 3 - The failure to present the certificate, within the period established in the previous paragraph, will imply the beginning of the procedures for suspension and subsequent cancellation of the registration or notification of the equipment.

§ 4 - In the event that the impossibility of certification is due to transient and partial problems, for the grant, alteration or revalidation of registration or notification of the equipment, a consolidated report shall 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.

§ 5 The testing laboratories and the OCP indicated in the previous paragraph shall be those accredited under 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.

§ 6 The consolidated report issued in § 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.

§ 7 The tests referred to in § 4 shall be based on the requirements contained in technical standards indicated in ANVISA IN Normative Instruction No. 49, of November 22, 2019, or their updates, which are applicable to the equipment.

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

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

1. - have been issued by laboratories accredited by institutions that are demonstrably signatories to the International Laboratory Accreditation Cooperation (ILAC); and

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

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

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

CONSOLIDATED REPORT

Art. 6 The consolidated report shall be issued on 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; IV - name and commercial model of the equipment;

4. - the name and address of the manufacturer;

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5. - Corporate name and address of the applicant for the report, in case it is different from that indicated in the previous item;

6. - description of the equipment, including its indication, purpose of use and the list of accessories and parts that have been tested in conjunction with the equipment;

7. - technical standards on which the test reports were based, with an indication of which items of those standards could not be verified;

8. - names of the testing laboratories used, accompanied by the names of their respective accrediting bodies and an indication of whether they are proven to be signatories to ILAC;

9. - results obtained in the tests for each verified item of the referenced technical standards, with indication whether the equipment tested is in conformity or not in accordance with the requirements of the item;

10. - indication of the items of the referenced technical standards that have not been checked;

11. - final conclusion , explaining whether there was a proven total compliance with the items evaluated of the indicated technical standards; and

12. - date, identification and signature of those responsible for issuing the report.

FINAL PROVISIONS

Art. 7 It is indispensable to maintain the certificate of conformity, according to technical standards indicated in ANVISA IN Normative Instruction No. 49, of November 22, 2019, or its updates, during the period of validity of the registration or product notification.

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

§ 2 - The lack of the certificate of conformity for more than 90 (ninety) days will imply the initiation of procedures for suspension and subsequent cancellation of the registration or notification of the equipment.

§ 3 The period provided for in the preceding paragraph shall not apply if the reason for the cancellation or suspension of the certificate of conformity derives from the finding of non-compliance with the technical standards, indicated in ANVISA IN Normative Instruction No. 49, of November 22, 2019, or its updates, and which are applicable to the equipment.

Art. 8 The following are hereby revoked:

1. - the Collegiate Board Resolution - RDC No. 27, of June 21, 2011, published in the Official Gazette No. 119, of June 22, 2011; and

2. - Article 5 of the Collegiate Board Resolution - RDC No. 423, of September 16, 2020, published in the Official Gazette No. 180, of September 18, 2020.

Article 9 This Resolution enters into force on October 1, 2021.

ANTONIO BARRA TORRES