

RESOLUTION - RDC Nº 692, DE 13 DE MAIO DE 2022

It provides for a fully electronic procedure for the notification to the National Health Surveillance Agency - ANVISA, of Risk Sanitizing Products I, and on the validity of the registrations of Risk Sanitizing Products 2

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 187, item VI and § 1 of the Internal Regulations, approved by the Collegiate Board Resolution - RDC No. 585, of December 10, 2021, resolves to adopt the following Resolution of the Board of Executive Officers, as resolved at a meeting held on May 12, 2022, and I, the Substitute Chief Executive Officer, determine its publication.

CHAPTER I INITIAL PROVISIONS

Section I Objective

Art. 1 This Resolution aims to reduce bureaucracy and expedite the procedures related to the notification of Risk Sanitizing Products I, as defined in Collegiate Board Resolution RDC No. 59, of December 17, 2010, or its updates.

Section II Scope

Art. 2 This Resolution applies to Sanitizing Products classified as Risk I and provides for the validity of registrations of Sanitizing Products classified as Risk 2.

Section III Definitions

Art. 3 For the purpose of this Resolution, the following definitions are adopted:

1. - notification: mandatory procedure of previously notifying, by means of electronic petition to ANVISA, the commercialization of Risk Sanitizing Products I; and
2. - Product identification number: number that must appear on the label and that has the purpose of assisting the sanitary control and traceability of the information related to its regularization with ANVISA, consisting of the number of the process generated in the proof of the respective "online" protocolization.

CHAPTER II PROCEDURES FOR NOTIFICATION

Section I General Requirements

Art. 4 For the purpose of this Resolution, the following requirements are adopted:

1. - notifications are now made exclusively in electronic form, in the "Electronic Petitioning and Collection System", of ANVISA;

1. - the necessary guidelines for the electronic procedure are available in the "Electronic Petitioning and Collection System" on the ANVISA website: <http://www.gov.br/anvisa>;
2. - the notification is only valid when an online protocol number is finalized and generated;
3. - the publicity of the notification is ensured by means of disclosure on the website of the World Wide Web - Internet, on the ANVISA website; and
4. - the company holding the notification is responsible for the notified products and for all the information provided relating to them, and must have supporting data attesting to the quality, safety, efficacy, suitability of the respective labelling statements, as well as the technical requirements established in the current legislation.

Section II Criteria

Art. 5 For the purpose of this Resolution, Sanitizing Products classified as Risk I, in order to be notified, must comply with the following criteria:

1. - does not contain prohibited, unauthorized or restricted substances with concentrations exceeding the limit established in current regulations;
2. - comply with the provisions of Law No. 6,360, of September 23, 1976, and Decree No. 8,077, of August 14, 2013 (or legal instruments that may replace them), and the Collegiate Board Resolution - RDC No. 694, of May 13, 2022, or their updates; and
3. - the name of the product is not listed only by category, nor does it contain the same name as another name that has already obtained previous notification and that is in force.

Section III Labelling

Art. 6 For the purpose of this Resolution, the following requirements for labelling are adopted:

1. - the label of Risk Sanitizing Products I must, in addition to complying with the provisions of current legislation, contain the Product Identifier Number, informed as follows:
"SANITIZING PRODUCT NOTIFIED AT ANVISA, N^o _."; and
2. - not to present on the labelling, labels, prospectuses or in any form of printed matter, expressions, geographical names, symbols, figures, drawings or any indications that allow false interpretation, error or doubt as to the origin, provenance, nature, composition or quality, which attribute to the product purposes or characteristics other than those which it actually possesses.

Section IV Amendments

Art. 7 The company is obliged to immediately notify ANVISA of any changes regarding the product provided for in the "Electronic Petitioning and Collection System", keeping the information duly updated and filed.

Single paragraph. The list of documents and the procedures necessary to make the changes are available in the "Electronic Petitioning and Collection System".

Section V Documentation

Art. 8 The documents generated at the end of the electronic procedure, either of the notification or of its alterations, including those contained in the Relations of Instruction Documents, as well as the attached files, must be printed, signed by the Technical Responsible and the Legal Representative and filed in the company itself, and must be available for sanitary surveillance actions.

Single paragraph. The documentation of the products covered by this Resolution is the subject of technical analysis within the scope of Product Monitoring Programs on the Market and Sanitary Control.

Section VI Validity of the Notification of Risk Sanitizing Products 1

Art. 9 Risk Sanitizing Products I are exempt from registration and their notification is exempt from revalidation.

§1 The maintenance of the regularization of the products referred to in the caput is linked to compliance with the technical requirements of this Resolution, the Resolution of the Collegiate Board of Directors - RDC No. 59, of December 17, 2010 (or its updates), the Resolution of the Collegiate Board of Directors - RDC No. 40, of June 5, 2008, or its updates, and the declaration of interest in the continuity of the commercialization of the products every 10 (ten) years, counted from the day of notification of the product in Anvisa.

§2 The interest in the continuity of the commercialization of the products must be declared in the electronic system available, in the last six months of the decade of regularization.

§3 The absence of the declaration of interest in the continuity of the commercialization results in the cancellation of the regularization of the product.

Section VII Cancellation

Art. 10. For the purpose of this Resolution, the following requirements are adopted for the request for cancellation of notification:

1. - the company holding the notification must request the cancellation of notifications of products that are no longer marketed; and
2. - Failure to comply with the provisions of this Resolution and other related regulations will result in the cancellation of the notification, without prejudice to other actions or measures provided for in the legislation in force.

§ 1 - ANVISA may determine the precautionary suspension of notification in cases of irregularity in the respective product, whenever duly justified public health reasons so require.

§ 2 - If the irregularity is not remedied or justified within the period granted by ANVISA, the notification may be canceled.

CHAPTER III VALIDITY OF THE REGISTRATION OF RISK SANITIZING PRODUCTS 2

Art. 11. The period of 10 (ten) years is established for the validity of the registration of sanitizing products of risk 2.

Art. 12. The validity periods of the registrations granted on a date prior to October 16, 2019 are extended to 10 (ten) years, counted from the granting of the registration, considering the registration revalidations already carried out.

CHAPTER IV FINAL PROVISIONS

Art. 13. The person responsible for the regularization of sanitizing products who intends to no longer market it in the Brazilian market must request the cancellation of its regularization to Anvisa.

Art. 14. ANVISA is not responsible for notification not received for technical reasons of computers, communication failures, congestion of communication lines, as well as other factors that make it impossible to transfer data.

Art. 15. Failure to comply with the provisions of this Resolution constitutes an infraction of a sanitary nature, subjecting the offender to proceedings and penalties provided for in Law No. 6,437, of August 20, 1977, or a legal instrument that may replace it, without prejudice to the applicable criminal and civil liabilities.

Art. 16. The following are hereby repealed:

1. - the Collegiate Board Resolution - RDC No. 42, of August 13, 2009, published in the Official Gazette No. 155, of August 14, 2009, Section 1, p. 82; and
2. - the Collegiate Board Resolution - RDC No. 313, of October 10, 2019, published in the Official Gazette No. 201, of October 16, 2019, Section 1, p.105.

Art. 17. This Resolution takes effect on June 1, 2022.

MEIRUZE SOUSA FREITAS
Substitute Chief Executive Officer