

**RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS - RDC No. 492, OF APRIL 15, 2021**

**(Published in DOU No. 74 of April 22, 2021)**

It provides for procedures related to post-regularization changes of sanitizing products.

**CHAPTER I**  
**OF THE INITIAL PROVISIONS**

Art. 1 This Resolution establishes procedures for post-regularization changes of sanitizing products.

**SECTION I**

**SCOPE**

Art. 2 This Resolution applies to sanitizing products.

**SECTION II**

**DEFINITIONS**

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

- layout: mode of distribution and arrangement of graphic elements in a given space or surface;
- notification: obligation to communicate in advance, by means of an electronic petition to Anvisa, the commercialization of Risk 1 sanitizing products; and
- post-regularization procedure: any change made in processes of sanitizing products of Risk 1 and Risk 2 after regularization.

**CHAPTER II**  
**OF THE GENERAL PROVISIONS**

Art. 4 The following post-regularization changes of the Sanitizing Products of Risk 1 and Risk 2 do not require a petition and do not depend on prior manifestation of Anvisa:

- 1 - alteration of data of the technical responsible in label, since already changed with the area responsible for the Authorization of Operation of Companies (AFE) of this Agency;
- 2 - change of address of the company holding the registration, manufacturer, importer or distributor on the label, provided that it has already changed with the area responsible for the AFE;

3 - modification of quantitative indications of packaging, provided that the type of primary packaging is not altered and the limits already established are met, according to the classification of the product as to sale and use (free sale or professional use).

4 - change of Customer Service number (SAC);

5 - alteration, deletion or inclusion in the label of the company's logo responsible for the regularization of the product; and

6 - change in the quantity of primary packaging contained in secondary packaging.

Single paragraph. Weeds are excluded from item VI.

Art. 5 The following petitions are subject to the simplified post-regularization procedure:

I - Amendment of Notification of Sanitizing Product Exempt from Registration; II - Change of Labeling of Risk Product 2;

- Cancellation of Risk Product Packaging 2 on request;

- Cancellation of Notification of Sanitizing Product Exempt from register;

- Cancellation of Risk Product Registration 2 on request; and VI - Cancellation of Risk Product Version 2 on request.

§ 1 - In the simplified procedure, the holder of the regularization must petition the change, but may implement it immediately, regardless of previous manifestation of ANVISA.

§ 2 - The petitions referred to in this article may be subject to documentary or fiscal evaluation at any time by ANVISA and, if necessary, additional information or clarification may be requested.

§ 3 - The petition mentioned in item I of the caput of this article refers exclusively to amendments that do not fall within the scope of article 4 of this Resolution.

§ 4 - The petition mentioned in item II of the caput of this article refers exclusively to the change of layout and dimensions of the label and the inclusion of promotional sayings, provided that no

mandatory or specific labeling requirement established in the specific rules in force is modified.

Art. 6 Changes to Risk 2 sanitizing products that do not fall under articles 4 and 5 of this Resolution are subject to the ordinary post-regularization procedure.

Single paragraph. In the ordinary procedure, the holder of the regularization must petition the amendment and wait for the favorable manifestation of ANVISA for implementation.

### **CHAPTER III**

#### **OF THE FINAL PROVISIONS**

Art. 7 The provisions of this Resolution apply to petitions after the regularization of sanitizing

products pending a decision by ANVISA on the date of its entry into force.

Art. 8 Failure to comply with the provisions of this Resolution constitutes a health infraction, under the terms of Law No. 6,437, of August 20, 1977, without prejudice to the applicable civil, administrative and criminal liability.

Art. 9 The following are hereby revoked:

- item 1.6 of item VI of the Annex to the Collegiate Board Resolution - RDC No. 208, of August 1, 2003, published in the Official Gazette No. 148, of August 4, 2003, Section 1, p. 31.

- item 12 of Annex II of the Collegiate Board Resolution - RDC No. 46, of February 20, 2002, published in the Official Gazette No. 35, of February 21, 2002, Section 1, p. 107.

- the indication "Technical Responsible: Name and number in the respective Professional Council" of Annex 5 of Ordinance No. 322, of July 28, 1997; and

- the indication "Name of the qualified technical responsible with the registration number in the respective professional council;" of Annex IV of Ordinance No. 152, of February 26, 1999.

Art. 10 This Resolution enters into force on June 1, 2021.

**ANTONIO BARRA TORRES**