LATINI GROUP
Integrated
Business
Solution

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RESOLUTION - RDC No. 640, OF MARCH 24, 2022

It provides for the regularization of disposable personal hygiene products intended for body cleanliness, which include brushes and rods for oral hygiene, dental floss and tape, disposable sanitary napkins, menstrual cups and flexible rods.

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the powers conferred on it by the arts. 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 and 3, of the Internal Regulations, approved by the Resolution of the Collegiate Board of Directors - RDC n° 585, of December 10, 2021, resolves to adopt the following Collegiate Board Resolution - RDC, as resolved at a meeting held on March 23, 2022, and I, the Chief Executive Officer, determine its publication:

CHAPTER I
INITIAL PROVISIONS

Section I
Objective

Art. 1 This Resolution establishes the definition, classification, technical and labeling requirements and electronic procedure for the regularization of brushes and rods for oral hygiene, dental floss and tapes, disposable sanitary napkins, menstrual cups and flexible rods, which are disposable personal hygiene products intended for body grooming.

Section II
Scope

Art. 2 This Resolution applies to disposable personal hygiene products, hereinafter referred to as disposable products, which include brushes and rods for oral hygiene, dental floss and tape, disposable sanitary napkins, menstrual cups and flexible rods, intended for body cleanliness.

Single paragraph. For the purposes of sanitary regularization, it is up to Anvisa to evaluate and, if applicable, submit new disposable personal hygiene products to this Resolution.

CHAPTER II
REQUIREMENTS FOR REGULARIZATION

Art. 3 Disposable products are exempt from registration and their commercialization in the national territory is conditioned to the procedure of prior communication to Anvisa by the company that owns the product.

§1 The sanitary regularization of disposable products must be carried out electronically, through Anvisa's electronic portal.

§2 Prior communication is the administrative procedure to be applied to inform Anvisa of the intention to market a product exempt from registration by means of notification.

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§3 The specific technical requirements for the regularization of disposable products, as well as the need for their presentation to Anvisa, are described in the table in Annex I of this Resolution.

§4 The publicity of the regularization of disposable products is ensured through disclosure on the electronic portal of Anvisa, after the end of the online protocol procedure.

§5 The guidelines necessary for the electronic procedure for the regularization of disposable products are available on Anvisa's electronic portal.

§6 The owner of the product must communicate the changes made to the product to Anvisa, through an electronic procedure, keeping the information duly updated.

§7 Anvisa may establish other forms of prior communication, including in non-electronic format, according to the interest of the administration.

Art. 4 The documents generated at the end of the electronic procedure must be kept in the enterprise.

Art. 5 The company must attach the Term of Responsibility to the transaction, duly signed by the Technical Responsible and Legal Representative of the company, according to Annex II.

Art.6 The regularization of disposable products, exempt from registration, is exempt from revalidation.

§1 The maintenance of the regularization of the products referred to in the caput is linked to compliance with this Resolution 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, by means of a specific form in the electronic petitioning system, 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.

Art. 7 The information presented in the regularization of the product, as well as its updates, are the sole responsibility of the company that owns the product, must comply with the provisions of the current sanitary legislation and are subject to sanitary control by Anvisa.

§1 The owner of the product must have supporting data that attest to the quality, safety and efficacy of its products and the suitability of the respective labeling statements, as well as compliance with the technical requirements established in the current legislation, which must be presented to the health surveillance bodies whenever requested.

§2 The owner of the product must ensure that the product does not constitute a risk to health when used during its period of validity, in accordance with the instructions for use and other information contained in the sales packaging of the product.

§3 The owner of the product who intends to no longer market it in the Brazilian market must request the cancellation of its regularization to Anvisa.

§4 The sanitary control of disposable products is carried out through verification of the information provided in the prior communication, market monitoring and inspection of the manufacturer, due to the health risk and the established in article No. 41 of Law No. 9,782, of January 26, 1999.

Art. 8 To manufacture or import the products referred to in this Resolution, companies must have an Operating Authorization from Anvisa for the activities and classes of products they wish to market and must have a license with the competent health authority.

Art. 9 Compliance with Good Manufacturing Practices is verified in the manufacturer and/or importer establishment through inspection carried out by the competent sanitary authority, in accordance with the Collegiate Board Resolution - RDC No. 48, of October 25, 2013, and its updates.

Art. 10. Disposable products containing ingredients that may migrate to the skin and/or mucous membranes must meet the requirements set forth in the following lists of substances in personal care products, cosmetics and perfumes:

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1. list of substances of preservative action allowed for personal care products, cosmetics and perfumes, approved by the Collegiate Board Resolution - RDC No. 528, of August 4, 2021, and its updates;

I. list of permitted coloring substances for personal care products, cosmetics and perfumes, approved by Collegiate Board Resolution - RDC No. 628, of March 10, 2022, and its updates;

II. list of substances that personal care products, cosmetics and perfumes must not contain except under the conditions and with the established restrictions, approved by the Collegiate Board Resolution - RDC No. 530, of August 4, 2021, and its updates;

III. list of ultraviolet filters allowed for personal care products, cosmetics and perfumes, approved by Collegiate Board Resolution - RDC No. 600, of February 9, 2022, and its updates; and

IV. list of substances that may not be used in personal care products, cosmetics and perfumes, approved by Collegiate Board Resolution - RDC No. 529, of August 4, 2021, and its updates.

Single paragraph. It is considered that fragrances and aromas are ingredients that migrate to the skin and/or mucous membranes.

CHAPTER III
REQUIREMENTS ON GENERAL MANDATORY LABELLING FOR DISPOSABLE PRODUCTS

Art.11. Disposable products must comply with the general mandatory labeling according to the items listed in Annex III.

Art.12. When the package is small and does not allow the inclusion of warnings and restrictions of use and/or instruction for use, these must be conveyed in an attached leaflet.

§1 In the event of the hypothesis that the caput deals with, the packaging must contain the following indications: "Warnings and restrictions of use: see attached leaflet" and or "Instruction for use: see attached leaflet".

§2 If the product contains primary and secondary packaging, one of the packages being small in a way that does not allow the inclusion of warnings and restrictions of use, it is allowed to replace this information by the description "Warnings and restrictions of use: see outer packaging" or "Warnings and restrictions of use: see inner packaging".

Art. 13. In the case of imported products, it is mandatory that all the labeling words listed in Annex III in the official language of Brazil (Portuguese) appear on the label, without prejudice to their parallel registration in other languages.

§1 Except for the provisions of the caput the composition of the product.

§2 When available, the qualitative description of the components of the formula must be declared by means of its generic designation, using the coding of substances established by the International Nomenclature of Cosmetic Ingredients (INCI).

§3 If the original label does not contain the required information, adequacy is accepted by means of a label or label containing the missing information.

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CHAPTER IV
SPECIFIC TECHNICAL REQUIREMENTS FOR REGULARIZATION OF BRUSHES FOR BUCCAL HYGIENE

Section I Definition

Art. 15. For the purpose of this Resolution, brushes for oral hygiene can be classified according to the purpose of use and/or age group and/or stiffness of the waxed area:

1. as for the purpose of use: manual, electrical, unitufo, interdental, for dentures, post-surgical, orthodontic and special for tongue hygiene;
2. as to the indication of the age group: adult or child use, as specified in the labeling statements; and
3. As for the stiffness of the waxed area: extra soft, soft, medium and hard.

Section III
Material

Art. 16. All the material that makes up the brush for oral hygiene must be non-toxic and suitable for its use, ensuring the physical robustness of the product and the health of the user.

Section IV
Packaging and Specific Labeling

Art. 17. The brush for oral hygiene should be packed in such a way as to preserve the quality of the product.

Art. 18. The labelling of brushes for oral hygiene shall include:

I- the indication of replacement of the brush every 3 (three) months after starting use or as dentist guidance;

II - the indication that the product is not perishable, replacing the indication of the shelf life, or indication of the shelf life, if applicable;

III- for children's products: the indication of child use, the presentation of the age group for which they are intended and the indication that the use should be supervised by an adult;

IV - the indication that the type of brush should be guided by the dentist; V - the indication as to the stiffness of the waxed area; and

VI - conservation care and storage place after use.

Section V
Tests

Art. 19. The following tests shall be carried out as provided below and kept in the undertaking at the disposal of the competent authority:

1. - measurement of the height/diameter of the bristle: it must be carried out with precision optical instruments or other apparatus with a reading accuracy of at least 0,1 mm (one tenth of a millimeter);
2. - measurement of the stiffness of the waxed area: it must be performed according to ISO 22254 ("Dentistry - Manual toothbrushes - Resistance of tufted portion to deflection") or its updates;
3. - voltage to remove the tuft: must be performed according to ISO 20126 ("Dentistry - Manual toothbrushes - General Requirements and Test Methods") or its updates;
4. - tests for radial filaments: must be performed for interdental brushes according to ISO 16409:2006 ("Manual interdental brushes") or its updates;

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5. - Shape of the bristle end: should be checked by means of optical microscope under dark field with maximum magnification reading of 50 (fifty) times. The tips of the bristles must be finished and may be smooth, feathered, flat, rounded and polished and 80% of the bristles applied to the brush must have a minimum acceptable finish; and

6. - electric brushes: must be evaluated according to ISO 20127 ("Dentistry - Powered toothbrushes - General Requirements and Test Methods") or its updates.

Section VI
Microbiological Requirements

Art. 20. Brushes for oral hygiene, because they are composed of synthetic and anhydrous materials, do not present susceptibility to microbiological growth, and their packaging should ensure protection against external contamination.

CHAPTER V
SPECIFIC TECHNICAL REQUIREMENTS FOR REGULARIZATION OF BRUSHES FOR BUCCAL HYGIENE

Section I
Definition

Art. 21. For the purpose of this Resolution, a rod for oral hygiene is defined as a mechanical instrument, which may or may not have electrical components and bristles, used to perform tongue hygiene.

Section II
Material

Art. 22. All the material that makes up the rod for oral hygiene must be non-toxic and suitable for its use, ensuring the physical robustness of the product and the health of the user.

Section III
Packaging and Specific Labeling

Art. 23. The oral hygiene rod should be packaged in such a way as to preserve the quality of the product.

Art. 24. The labelling of the stems for oral hygiene shall state:

1.the indication of replacement of the rod every 3 (three) months after starting use or as guidance from the dentist;

II - the indication that the product is not perishable, replacing the indication of the shelf life, or indication of the shelf life, if applicable;

1. for children's products: the indication of child use, the presentation of the age group for which they are intended and the indication that the use should be supervised by an adult; and

III- conservation care and storage place after use.

Section IV
Tests

Art. 25. The following tests shall be carried out on bristled oral hygiene rods and kept in the undertaking at the disposal of the competent authority:

1.- measurement of the height/diameter of the bristle: it must be carried out with precision optical instruments or other apparatus with a reading accuracy of at least 0,1 mm (one tenth of a millimetre);

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2.- measurement of the stiffness of the waxed area: it must be performed according to ISO 22254 ("Dentistry - Manual toothbrushes - Resistance of tufted portion to deflection") or its updates;

3.- voltage to remove the tuft: must be carried out according to ISO 20126 ("Dentistry - Manual toothbrushes - General Requirements and Test Methods") or its updates; and

4.- Shape of the bristle end: should be checked by means of optical microscope under dark field with maximum magnification reading of 50 (fifty) times. The tips of the bristles must be finished, and may be smooth, feathered, flat, rounded and polished and 80% (eighty percent) of the bristles applied to the brush must present minimum acceptable finish.

Section V
Microbiological Requirements

Art. 26. The stems for oral hygiene, because they are composed of synthetic and anhydrous materials, do not present susceptibility to microbiological growth, and their packaging should ensure protection against external contamination.

CHAPTER VI
SPECIFIC TECHNICAL REQUIREMENTS FOR THE REGULARIZATION OF DISPOSABLE SANITARY PADS INTENDED FOR BODY GROOMING

Section I
Definitions

Art. 27. For the purpose of this Resolution, the following definitions are adopted:

1.- disposable absorbent products for external use: articles intended for body cleanliness, applied directly to the skin, for the purpose of absorbing or retaining excretions and organic secretions, such as urine, feces, breast milk and those of a menstrual and intermenstrual nature; and

2.- Disposable absorbent products for intravaginal use: articles intended to absorb or retain menstrual and intermenstrual excretions and secretions, applied by vaginal insertion.

Single paragraph. Female sanitary napkins for external use, baby diapers, adult diapers, incontinence sanitary napkins and breast milk pads are included in the product group referred to in item I.

Section II
Material

Art. 28. Disposable absorbent products shall be composed of hydrophilic cotton fibres and/or other absorbent materials which do not contain any pharmacologically active ingredients.

Single paragraph. Disposable absorbent products for external use may also contain ingredients such as fragrances and odor inhibitors. These ingredients cannot be added to tampons for internal use.

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Section III
Security Requirements

Art. 29. The holder of the product shall ensure the safety of the finished product by assessing the following requirements:

1.- Chemical Safety Information Sheet (MSDS) and other information related to the safety of each raw material used;

2.- for fragrances, a report of safety of the raw material issued by the supplier, ensuring its safety, in accordance with the standards established by competent regulatory bodies, such as IFRA - International Fragrance Association; and

3.- for intravaginal sanitary pads, in addition to the requirements laid down in items I and II, cytotoxicity and irritation tests of the vaginal mucosa should be performed on the finished product.

Single paragraph. Where the information described in items I and II is not available or inconclusive, safety shall be ensured by carrying out the following tests on the finished product:

1.- primary skin irritation;

2.- repeated skin irritation; and III - dermal sensitization.

Art. 30. The owner of the product must have a technical opinion on the safety of the product based on the requirements described in article 29 and submit to Anvisa a summary that attests to the safety of use of the finished product.

Section IV
Microbiological Requirements

Section I
Definitions

Art. 31. The holder of the product shall ensure the following microbiological limits for the finished product:

1.- disposable absorbent products for external use: absence of Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans and, in the case of breast pads, absence of Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans and Clostridium sp, based on evaluations carried out with a sample of 10g (ten grams); and

2.- disposable absorbent products for intravaginal use: absence of Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Clostridium sp and Candida albicans, based on evaluations performed with a sample of 10g (ten grams).

§ 1 - For the products referred to in item I, the count of mesophilic aerobic microorganisms shall not exceed 1000 CFU (one thousand colony-forming units) per gram of sample and the count of fungi and yeasts shall not exceed 100 CFU (one hundred colony-forming units) per gram of sample.

§ 2 For the products referred to in item II, the count of mesophilic aerobic microorganisms shall not exceed 500 CFU (five hundred colony-forming units) per gram of sample and the count of fungi and yeasts shall not exceed 100 CFU (one hundred colony-forming units) per gram of sample.

Section V
Specific Labelling

Art. 32. The labeling of disposable absorbent products for intravaginal use should include:
I - instructions that clearly guide the user about Toxic Shock Syndrome (TSS);

1.- mode of use;

2.- guidance on the need to use the appropriate size for each menstrual flow;

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3.- description of the characteristics of the products of its brand as to the sizes and type of menstrual flow, defined as a function of the amount of absorption in grams;

4.- frequency of product exchange;

5. - importance of personal hygiene, especially washing hands before and after the insertion of an intravaginal pad;

6.- information on the need to use only one tampon, each time;

7.- guidance for the user to make sure that the absorbent has been removed at each change of the product and when menstruation ends; and

8.- guidance for the user to seek medical help in case of difficulty for total withdrawal of the product.

CHAPTER VII
SPECIFIC TECHNICAL REQUIREMENTS FOR REGULARIZATION OF MENSTRUAL CUPS

Section I
Definition

Art. 33. For the purpose of this Resolution, a menstrual cup is defined as an intravaginal device used to collect menstrual flow.

Section II
Material

Art. 34. All the material that makes up the menstrual cup should be non-toxic and suitable for your use.

Single paragraph - Menstrual cups should be free of ingredients such as fragrances and odor inhibitors.

Section III
Security Requirements

Art. 35. The holder of the product shall ensure safety by assessing the following requirements on the finished product:

I - cytotoxicity tests according to ISO 10993-5; II - irritation of the vaginal mucosa in humans; and

III - dermal sensitization.

Single paragraph. The tests described in items II and III, when performed in humans, must have a minimum of 30 (thirty) volunteers.

Art. 36. The owner of the product must have a technical opinion on the safety of the product based on the requirements described in article 35 and submit to Anvisa a summary that attests to the safety of use of the finished product.

Section IV
Microbiological Requirements

Art. 37. The holder of the product must ensure the following microbiological limits for the finished product, based on evaluations carried out with a sample of 10g (ten grams): absence of Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Clostridium sp and Candida albicans.

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Single paragraph. The count of mesophilic aerobic microorganisms shall not exceed 500 CFU (five hundred colony-forming units) per gram of sample and the count of fungi and yeasts shall not exceed 100 CFU (one hundred colony-forming units) per gram of sample.

Section V
Specific Labelling

Art. 38. The labelling of menstrual collecting products shall include:

1.- instructions that clearly guide the user about TSS (Toxic Shock Syndrome);

2.- mode of use containing the frequency of removal of the product for disposal of the contents menstrual;

3.- guidance on the need to use the appropriate size for each menstrual flow;

4.- description of the characteristics of the products of your brand as to the sizes and type of menstrual flow;

5.- time for disposal of the menstrual cup, based on tests that determine that the product maintains its properties, considering the conditions of use of the product;

6.- importance of personal hygiene, especially washing hands before and after inserting the menstrual cup;

7.- guidance for the user to make sure that the collector has been removed within the deadline stipulated by the manufacturer;

8.- guidance for the user to seek medical help in case of difficulty to remove the product;

IX- indication of conservation care;

1.- indication of the appropriate packaging and place of storage after use; and

2.- guidance for the user with prolapse, retroversion or anteflexion of the uterus to consult a doctor before starting the use of the product.

CHAPTER VIII
SPECIFIC TECHNICAL REQUIREMENTS FOR REGULARIZATION OF DENTAL WIRES AND TAPES

Section I
Definition

Art. 39. For the purpose of this Resolution, dental wires and tapes are defined as nylon or tape, polypropylene (PP), polytetrafluoroethylene (PTFE) or other appropriate material, and may be covered by sliding, flavoring and/or other ingredients intended to perform oral hygiene between the teeth, in orthodontic appliances and / or prostheses, in order to remove residues of food and / or plaque, avoiding the accumulation of plaque and consequently the formation of cavities and gum problems.

§ 1 - The addition of fluoride to dental wires and tapes is allowed as long as it does not exceed the maximum permissible concentration of 0.15% (fifteen hundredths' percent).

§ 2 - The regularization of dental wires and tapes intended for children must follow the present norm.

Section II
Material

Art. 40. All material that makes up the dental wires and tapes must be non-toxic and suitable for your use.

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Section III
Packaging and Specific Labeling

Art. 41. Dental threads and tapes must be packed in such a way as to preserve the quality of the product.

Art. 42. The labelling of dental threads and tapes shall include:

I - instructions as to the correct use of the product in order to ensure the effectiveness and safety of its use;

II - in the case of dental floss and tape plus fluoride, indication of the fluoride compound used, its concentration in ppm (part per million) and inclusion of the phrase "Do not use in children under 2 years"; and

III- indication that the use in children should be supervised by an adult.

Section IV
Security Requirements

Art. 43. The holder of the product shall ensure the safety of the finished product by assessing the following requirements:

1.- Chemical Safety Data Sheet (MSDS) and other information related to the safety of each raw material used; and

2.- for flavorings, report of safety of the raw material issued by the supplier, ensuring its safety, in accordance with the standards established by competent regulatory bodies, such as IFRA - International Fragrance Association.

Section V
Microbiological Requirements

Art. 44. The holder of the product must ensure the microbiological limits for the finished product in accordance with the specific technical regulation that establishes the microbiological control parameters for personal care products, cosmetics and perfumes, approved by the Collegiate Board Resolution - RDC No. 630, of March 10, 2022, and its updates.

CHAPTER IX
SPECIFIC TECHNICAL REQUIREMENTS FOR REGULARIZATION OF FLEXIBLE RODS

Section I
Definition

Art. 45. For the purpose of this Resolution, flexible rods are defined as toiletries composed of a flexible rod with the ends covered with hydrophilic cotton fiber or other absorbent, non-sterile materials, used primarily to aid body cleanliness.

Section II
Material

Art. 46. All the material that makes up the flexible rods must be non-toxic and suitable for its use.

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Section III
Packaging and Specific Labeling

Packaging and Specific Labeling

Art. 47. Flexible rods must be packed in such a way as to preserve the quality of the product. Art. 48. The labelling of flexible rods shall indicate that:

1.- the product should not be inserted into the ear canal due to the risk of perforation of the eardrum;

2.- children should not use the product without adult supervision; and

3.- The product should not be inserted deep into the nostrils to avoid injury.

Section IV
Microbiological Requirements

Art. 49. The holder of the product shall ensure the microbiological limits for the finished product in compliance with the specific technical regulation that establishes the parameters of microbiological control for personal care products, cosmetics and perfumes, approved by the Collegiate Board Resolution - RDC No. 630, of March 10, 2022, and its updates.

CHAPTER X
OF THE FINAL PROVISIONS

Art. 50. The authenticity and veracity of the information provided to Anvisa are the responsibility of the owner of the product, and any irregularity detected by Anvisa, contrary to the provisions of the relevant health legislation, 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, resulting in the cancellation of the prior marketing notice of the product under the terms of this Resolution.

Art. 51. The following rules are hereby repealed:

1.- Collegiate Board Resolution - RDC No. 142, of March 17, 2017; and

2.- Collegiate Board Resolution - RDC No. 178, of September 26, 2017. Art. 52. This Resolution enters into force on May 2, 2022.

ANTONIO BARRA TORRES

ANNEX I
SPECIFIC TECHNICAL REQUIREMENTS FOR THE REGULARIZATION OF DISPOSABLE PRODUCTS

Mandatory Requirements	In the undertaking at the disposal of the competent authority	Present for regularization of the product	Observations
1. Trade Name: Product	X	X	
2. Product Category	X	X	
3. Purpose of the product	X	X	
4. Physico-chemical Technical Specifications of raw materials	X (complete)		
5. Physico-chemical technical specifications of the finished product	X (complete)	X (resume)	

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6. Microbiological specifications of raw materials	X (complete)		When applicable
7. Microbiological specifications of the finished product	X (complete)	X (resume)	When applicable
8. Disclaimer	X	X	
9. Usage safety data (proof of safety)	X (complete)	X (resume) When required by the standard	
10. Data proving the benefits attributed to the product (proof of efficacy)	X (complete)		When justified by the nature of the benefit of the product and where it appears on the labelling.
11. Stability data	X (complete)	X (resume)	Methodology and conclusions that guarantee the declared shelf life, where applicable.
12. Data proving the shelf life of the menstrual cup after initiation of use.	X (complete)	X (resume)	Methodology, results and conclusions that guarantee the declared disposal period
13. Label or labeling Art Project	X		Company must enter in the system for inspection purposes, and may be after the regularization of the product.
14. Manufacturing Process	X		According to the Standards of Good Manufacturing and Control Practices provided for in the legislation.
15. Technical specifications of the packaging material	X		
16. Sistema de codificação de lote	X		Information to interpret the coding system.
17. Registration/Company Authorization/Certificate of Registration of the Establishment	X		According to current legislation.
18. Composition	X	X	When available, the qualitative description of the components of the formula shall be declared by means of its generic designation, using the coding of substances established by the International Nomenclature of Cosmetic Ingredients (INCI).

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19. How to use	X	X	

ANNEX II

Disclaimer		
The company (describe the corporate name of the company), duly authorized by the National Health Surveillance Agency - Anvisa under the number (describe the number of operating authorization), in this act represented by its Technical Responsible and its Legal Representative, declares that the product (describe the name of the product and brand) meets the regulations and other legal provisions regarding the control of process and finished product and other technical parameters related to the Good Manufacturing Practices pertinent to the product category.		
The company declares that it has supporting data that attest to the safety and efficacy of the proposed purpose of the product and that it does not constitute a risk to health when used in accordance with the instructions for use and other measures contained in the sales packaging of the product during its period of validity. The company assumes before Anvisa that the product meets the specific technical requirements established in the current legislation, as well as the lists of substances, the labeling standards and the correct classification of the product. It declares that the labelling does not contain therapeutic indications and particulars, nor names and indications which mislead, deceive or confuse as to its origin, origin, composition, purpose or safety.		
Declares to be aware that the regularized product is subject to audit, market monitoring and registration inspection by the competent health authority and, if irregularity is found, the product will be canceled, without prejudice to the applicable civil, administrative and criminal responsibilities. The undersigned assume, before this body, that non-compliance with the provisions of current legislation and its updates constitutes a health infraction, with violators being subject to the penalties provided for by law.		
Date	Legal Representative	Technical Manager
_____	_____	_____

ANNEX III
REQUIREMENTS ON GENERAL MANDATORY LABELLING FOR DISPOSABLE PRODUCTS

REF.	ITEM
1.	Name of the product and group/type to which it belongs if it is not implied in the name
2.	Brand
3.	Company Operating Authorization - AFE
4.	Plot or Departure
5.	Shelf life (except in cases where the standard dispenses)
6.	Content
7.	Country of origin
8.	Holder of the product and CNPJ
9.	Domicile of the owner of the product
10	Instruction for use
11	Specific Warnings and Restrictions on Use
12	Specific Labelling
13	Composition
14	Communication channel with the consumer

1 - As a composition of the product must be informed, minimally, the ingredients that may migrate to the skin and or mucous membranes.

2- When available, the qualitative description of the components of the formula must be declared by means of its generic designation, using the coding of substances established by the International Nomenclature of Cosmetic Ingredients (INCI).