

A GUIDE TO

# BRAZIL



**Toiletry, Perfume and Cosmetic  
Products Compliance Requirements**



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## Overview

This guide does not intend to exhaust the subject, but was created in order to facilitate the export of Toiletries, Perfumes and Cosmetics to Brazil. It shows the regulatory authorities, main requirements/laws that need to be taken into account, conformity assessment procedures and government bodies, ministries, departments or any authority involved in the process.

All the documents mentioned in this guide are applied to the scope. Regulations are considered mandatory while Standards, on the other hand, are voluntary unless “Incorporated by Reference” in a regulation.

The responsibility for updating the documents (Regulations/Standards) cited in this guide rests with the Regulation Authorities / Standardization Bodies. Therefore it is recommended that the version of any document is always checked through the corresponding website. The Brazilian Enquiry Point could also provide more information through the e-mail [barreirastecnicas@inmetro.gov.br](mailto:barreirastecnicas@inmetro.gov.br).

## How To Use This Guide

- Regulations are mandatory
- Standards are voluntary (unless “Incorporated by Reference” in a regulation)
- Guidelines may be voluntary (but are often de facto industry standards)

## Scope

This guide addresses the compliance requirements for Toiletries, Perfumes and Cosmetics. The National Health Surveillance Agency (Anvisa) defines those products as preparations of natural or synthetic substances, for external use on diverse parts of the human body, skin, hair, nails, lips, external genital organs, teeth, and mucous membranes of the oral cavity, with the sole or main objective of cleaning them, perfume them, alter their appearance and/or correct body odors, and protect and maintain them in good shape. According to Resolution RDC 7/2015, products can be classified under group 1 or group 2, depending on whether proof of their basic properties, safety and effectiveness and detailed information on use and on restrictions are necessary or not. Products that fall typically under group 1 include, among others, skin moisturizers (without sunscreen; except those for stretch marks), face cleansing creams, lotions, gels and oils (except those for acne skin), perfumes, lipsticks (without sunscreen), fingernail polishes, eye and facial makeup preparations (without sunscreen), eyelash mascara, cleansing shampoos and hair conditioners

(except those antidandruff, for hair loss prevention or that claim other benefit), bath salts, oils, gel capsules and foam, facial or body soap (except those with antiseptic action), deodorants (except those antiperspirants), toothpastes (except those containing fluoride; for prevention of dental plaque or tooth decay; indicated for sensitive teeth; chemical bleachers) . The mentioned exceptions fall under group 2, as well as hydrogen peroxide 10 to 40 volumes (including creamy products, except those for medicinal use); children's products,; sunscreen lotions and creams; products for straightening, curling and/or dyeing hair; products for wrinkles; antiseptic soap; insect repellent products, among others.

## The regulatory framework in Brazil

A large number of agencies at federal level (regulatory agencies) have the authority to prepare technical regulations in a specific competence area. Technical regulations are always published in the Official Journal and, in general, are based on international standards. The agencies may start the preparation of a technical regulation ex officio or at the request of a third part. If the competent authority considers it necessary, a draft regulation is developed and published in the Official Journal, after an impact evaluation assessment of the new technical regulation. Technical regulations take the form of laws, decrees, resolutions and ordinances etc. Brazil normally allows a period of at least six months between the publication and their entry into force in order to enable interested parties to become acquainted with them.

Public audiences or hearings are also a way to promote public consultation on technical regulations. In parallel, if the technical regulation is considered to have effects on trade, it is notified to WTO to allow Members to make comments in writing.

### **Instituto Nacional de Metrologia, Qualidade e Tecnologia – INMETRO**

The National Institute of Metrology, Quality and Technology (Inmetro) is the Brazilian Enquiry Point responsible for submitting to the WTO the notification of draft technical regulations under the TBT Agreement. The technical regulation projects that have an impact on international trade are notified, even if those regulations are identical to international standards. It should be noted that the vast majority of Brazilian technical regulations are based on international standards and product performance criteria. In addition to its regulations and conformity assessment procedures, Inmetro notify to WTO technical requirements of other government agencies, such as the National Health Surveillance Agency (Anvisa), Ministry of Agriculture, Livestock and Supply (Mapa) the National Petroleum Agency (ANP), the Ministry of Mines and Energy (MME), the National Telecommunications Agency (Anatel), among others.

Inmetro is responsible for receiving comments from other countries on draft regulations. Both domestic and foreign private sectors can make comments and participate in the discussions. After all comments and suggestions are analyzed, the specific competence agency decides whether to adopt the technical regulation, taking into account or not the comments/suggestions received.

In 2007, Brazil adopted The Brazilian Guide on Good Regulatory Practices , to help preparing, review, revoke, and disseminate technical regulations. This encourages transparency and consistency on the improvement of regulatory practices. The Guide recommends that public bodies focus on safety, health, environment and consumer protection issues. There is not, however, mandatory rules of general application for drawing up technical regulations. Each entity is responsible for the development of technical regulations based on their own procedures.

Inmetro and all other regulatory bodies can develop and adopt assessment conformity procedures. The process by which conformity assessment programs are carried out is similar to that used in the case of technical regulations. There is a period of public consultation and the measure is published in the Official Journal. Conformity assessment procedures that carry considerable economic impact are also notified to the WTO by Inmetro.

Based on the specific characteristics of the product, conformity assessment can be performed by certification, labeling, inspection, sampling and/or a supplier's declaration of conformity. Certification is performed by third parties, in general accredited private bodies. Products and services subject to mandatory certification are those that can affect health and consumer safety or the environment.

Inmetro recognizes the certification of products and systems carried by foreign product certification bodies (OCP) which have a memorandum of understanding with a Brazilian OCP or with which Inmetro has signed an agreement. Furthermore, Inmetro is the national authority for the accreditation of certification, inspection and training bodies and calibration and testing laboratories.

It is worth explaining that the National Institute of Metrology, Standardization and Industrial Quality (Inmetro) is a federal agency under the Ministry of Industry, Trade and Services, which acts as the Executive Secretariat of the National Council of Metrology, Standardization and Industrial Quality (Conmetro), an interministerial collegiate, which is the regulatory body of the National System of Metrology, Standardization and Industrial Quality (Sinmetro). Sinmetro, Conmetro and Inmetro make up an articulated systemic structure, created by Law 5.966 of December 11, 1973. On the occasion Inmetro replaced the then existing National Institute of Weights and Measures (INPM) and, with the new legal responsibilities, increased significantly its field of action, always in service of Brazilian society. Main information on Inmetro can be obtained at [www.inmetro.gov.br](http://www.inmetro.gov.br).

## **Agência Nacional de Vigilância Sanitária – Anvisa**

The Brazilian Health Regulatory Agency (Anvisa), an agency under the Ministry of Health, was established by Law no. 9782 of January 26, 1999. It aims at promoting and protecting the population's health through the sanitary control of production and consumption of goods and services subject to health surveillance, including the environment, processes, inputs and technologies related to them, as well as the control of ports, airports, border crossings and customs enclosures. Main information about Anvisa can be obtained in their website: <http://portal.anvisa.gov.br/>.

## **Associação Brasileira de Normas Técnicas – ABNT**

The body responsible for developing voluntary technical standards in Brazil is the Brazilian Association of Technical Standards (ABNT), a non-profit, non-governmental body that receives financial support from the Federal Government, founded in 1940. ABNT represents Brazil in the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and regional standardization forums such as the Pan American Standards Commission (COPANT) and MERCOSUR Standardization Association (AMN). The Brazilian standards development process follows the WTO good practice code in order to guarantee transparency.

In order to ensure that the content of the rules is up to date, standards older than five years are reviewed. The review process follows international guidelines and includes public consultation through the ABNT website. During the consultation period, interested parties have the opportunity to express an opinion to whether the standard should be confirmed, updated or canceled. Main information on ABNT can be obtained at [www.abnt.org.br](http://www.abnt.org.br).

## **Associação Brasileira da Indústria de Higiene Pessoal, Perfumaria e Cosméticos – ABIHPEC**

The Brazilian Association of the Toiletry, Perfume and Cosmetics Industry (ABIHPEC) was created in 1995 as the natural evolution of an association from the State of São Paulo, founded in 1941. It brings together around 400 companies of different sizes, which correspond to 94% of the sector's turnover. Main information on ABIHPEC can be obtained at <https://abihpec.org.br/>.

ABIHPEC plays an important sectorial role within ABNT. In 2004, ABIHPEC installed ABNT committee/CB-57 – Toiletry, Perfumery and Cosmetics to address industry standards including products, processes, services and raw materials concerning terminology, requirements, classification and test methods, best practices and other generalities. CB-57 is the official

national standardization forum for the toiletries, perfumery and cosmetics industry, according to award granted by Resolution no. 7 of August, 24 1992, of the National Council of Metrology, Standardization and Industrial Quality (Conmetro). CB-57 participates in the ISO committee TC 217, which covers HPPC products, initially as an Observer Member, in 2004, and as a Participant Member, as from August 1, 2011.

## Regulation of Toiletries, Perfumes and Cosmetics

The Ministry of Health controls the manufacture and import of all Toiletries, Perfumes and Cosmetics in Brazil since the publication of Law no. 6.360 of September 23, 1976 and its Decree no. 79.094 of January 5, 1977, revoked by Decree no. 8077 of August 14, 2013. The intention is to ensure the safety and product quality for the population's health protection.

The Brazilian Health Regulatory Agency (Anvisa) is the main authority and responsible for documents in the scope. Their Department of Cosmetics, under the Directorate of Coordination of the National Health Surveillance System (DSNVS), address all pre-market regulation matters concerning toiletries, cosmetics and perfumes and also those relating to raw materials, labeling and technological innovations of such products. Authorization of the operation of manufacturers and importers and post-market matters at national level, including compliance, enforcement and cosmetovigilance are under the responsibility of Directorate of Health Control and Monitoring (DIMON), which acts in conjunction with the state and municipal health surveillance secretariats.

Brazil is a MERCOSUR Member State and most of the health requirements for Toiletries, Perfumes and Cosmetics (Higiene Pessoal, Perfumes e Cosméticos, HPPC, in Portuguese) products are harmonized and recognized by MERCOSUR regulations since 2004. It is important to mention that MERCOSUR resolutions enter into force after being internalized through national mechanisms and published in the Official Journal of each Member State.

Also in compliance with Law N° 6.360/76, only companies authorized by the Ministry of Health and licensed by the Health Agency of the Federal States where they are located can extract, produce, manufacture, process, synthesize, purify fraction, pack, repack, import, export, store or ship cosmetics in Brazil.



## Federal Regulatory Authorities and Technical Regulations (Mandatory)

| Agency  | Scope   |
|---|---|
| Brazilian Health Regulatory Agency (Anvisa)   | Toiletries, Perfumes and Cosmetics sanitary regulation including: authorization of the operation of manufacturers and importers; good manufacturing practices; marketing authorization, post-market sanitary control and sanitary border control. |
| National Institute of Metrology, Quality and Technology (Inmetro)                             | Product safety, children's products, cosmetic packaging and labeling relating to weight and volume, unfair trade practices and product performance.   |
| Brazilian Customs (Receita Federal Brasileira)  | Border control and country of origin (for most imported products, licensing, and certification).  |
| The Chief of Staff of the Presidency of the Republic (Casa Civil da Presidência da República) | Consumer Law.   |

## Regulatory Authority of Toiletries, Perfumes and Cosmetics

### Brazilian Health Regulatory Agency – Anvisa

A list of documents published by Anvisa can be found in the Appendix I of this guide or can be viewed directly in the Anvisa database through the link [http://portal2.saude.gov.br/saudelegis/LEG\\_NORMA\\_PESQ\\_CONSULTA.CFM](http://portal2.saude.gov.br/saudelegis/LEG_NORMA_PESQ_CONSULTA.CFM).

### Anvisa's Product Market Authorization Process

#### Overview

There are two ways for Toiletries, Perfumes and Cosmetics to be authorized at Brazilian Market: registration and prior notification of a product exempted of registration.

Registration is the legal act that recognizes the suitability of a product to sanitary legislation, granted by the Brazilian Health Regulatory Agency – Anvisa. It is a control applied prior to commercialization of products that could present higher health risks. After reviewing the dossier, the Agency publicizes the awarded registration in the Official Journal (Diário Oficial da União - DOU) as proof of the concession by Anvisa. After this, the product is authorized to be sold in Brazil.

Prior notification of a product exempted of registration is the administrative procedure to be applied to inform Anvisa of the intention to commercialize a product exempted

from registration by means of electronic communication. About 97% of the Toiletries, Perfumes and Cosmetics products that have the commercialization authorized in Brazil follow this route.

To have Market Authorization, products subject to health surveillance, must comply with the criteria laid down by Brazilian laws and with the specific regulations established by Anvisa. These criteria aim at minimizing possible risks associated with the product in question.

The manufacturer or importer company is responsible for the quality and safety of the products authorized by Anvisa.

### Regulation involved

Anvisa's Toiletries, Perfumes and Cosmetics Technical Regulation RDC nº 07/2015 is the document that lays down the general product characteristics and technical requirements. It can be accessed through link <http://portal.anvisa.gov.br/legislacao#/visualizar/29327>, and other specific regulation can be accessed through link <http://portal.anvisa.gov.br/legislacao#>.

### Scope

Only Products listed in Annex VIII of Technical Regulation RDC 07/2015, are subject to the Anvisa registration procedure. They are: sunscreen and suntan lotions, children's products, hair straighteners, insect repellents and antiseptic gels for the hands.

These Products have specific indications, whose characteristics require proof of safety and/or efficacy, as well as information on care, mode and restrictions of use.

### Process flowchart for registration

The registration must be requested by the interested company through the Petitioning System (<http://portal.anvisa.gov.br/sistema-de-peticionamento>), following the steps below:

#### **STEP 1 - Company Registration**

The Company Registration is the first step to have access to the Petitioning System and should be used to register private companies that provide products or services regulated by Anvisa and to register the users with bond of representation with these companies.

More information about the registration process can be obtained through the link (only in Portuguese) <http://portal.anvisa.gov.br/cadastramento>.

## STEP 2 - Change of the size of the company (optional)

Anvisa calculates the fees applied to the process according to the size of the company. By default, Anvisa classifies all companies as big size and, if it is not the case, it could be changed in this step.

More information about company size classification can be obtained through the link (only in Portuguese) <http://portal.anvisa.gov.br/porte-de-empresa>.

## STEP 3 - Request

Before accessing the Requesting System it is recommended that the interested party identify the Subject Code (<http://portal.anvisa.gov.br/sistema-consulta-de-assuntos>) related to their request, since the entire request process will be developed under this code.

During the process, the interested party will be driven to the type of petition of the chosen Subject Code.

More information about de Request can be obtained through the link (only in Portuguese) <http://portal.anvisa.gov.br/peticionamento>.

## STEP 4 - Fees

At the end of the petition process, a payment document (Guia de Recolhimento da União - GRU) will be electronically generated so that the taxes related to the process (Taxa de Fiscalização de Vigilância Sanitária - TFVS) can be covered. The corresponding fee is determined by Interministerial Ordinance N°. 701, 31 August, 2015 or its updated versions.

More information about fees can be obtained through the link (only in Portuguese) <http://portal.anvisa.gov.br/taxas1>.

## STEP 5 – Document protocol

After payment of the GRU, the interested party must gather the documentation requested according to the checklist of the chosen Subject Code and send to Anvisa, containing the following address (only original documents are accepted):

*À Agência Nacional de Vigilância Sanitária*

*Aos cuidados da Gerência de Gestão Documental*

*Ref: (Process Number)*

*SIA, trecho 5, área especial 57*

*CEP 71.205-050*

*Brasília – DF, Brasil*

More information about document protocol can be obtained through the link (only in Portuguese) <http://portal.anvisa.gov.br/protocolo>.

#### Documents required by the process

The documents required by the process are listed in the checklist of the Subject Code. Processes will be rejected if documents are missing or filled wrongly.

#### How to follow the process

Progress of the request can be followed by checking Document Status in the system, through the link <http://portal.anvisa.gov.br/consulta-a-situacao-de-documentos1>.

More information on how to follow the process can be obtained through the link (only in Portuguese) <http://portal.anvisa.gov.br/acompanhamento>.

#### How to know the result

Publication of the awarded registration in the Official Journal (Diario Oficial da União - DOU) represents proof of the concession by Anvisa. After this, the product is authorized to be sold in Brazil.

The Brazilian Official Journal (DOU) can be accessed through the link <http://portal.imprensa-nacional.gov.br/>.

The product must, necessarily, correspond to what was evaluated and authorized by Anvisa, according to the registration process protocol. Furthermore, no change is allowed without prior authorization of Anvisa, as established in art. 13 of the [Law N° 6360/1976](#).

Anvisa may, at any time and in its discretion, require additional evidence or tests in case that new events raise concerns about the product, even after granting its registration.

#### Validity of the process

Registration is valid for five years from the date of publication in the Official Journal (DOU).

#### Process flowchart for prior notification of a product exempted of registration

The prior notification of a product exempted of registration must be requested by the interested company through two systems: (1) the [Petitioning System](#) and (2) [System for notification of Toiletries, Perfumes and Cosmetics exempted of registration – SGAS](#) following the steps below:

## STEP 1 - Company Registration

The Company Registration is the first step to have access to the Petitioning System and should be used to register private companies that provide products or services regulated by Anvisa and to register the users with bond of representation with these companies.

More information about the registration process can be obtained through the link (only in Portuguese) <http://portal.anvisa.gov.br/cadastramento>.

## STEP 2 - Change of the size of the company (optional)

Anvisa calculates the fees applied to the process according to the size of the company. By default, Anvisa classifies all companies as big size and, if it is not the case, it could be changed in this step.

More information about company size classification can be obtained through the link (only in Portuguese) <http://portal.anvisa.gov.br/porte-de-empresa>.

## STEP 3 – Request

From this point the notification of a product exempt from registration must be made in System for notification of Toiletries, Perfumes and Cosmetics exempted of registration – SGAS following the steps required [at the system](#).

## STEP 4 - Fees

At the end of the petition process, a payment document (Guia de Recolhimento da União - GRU) will be electronically generated so that the taxes related to the process (Taxa de Fiscalização de Vigilância Sanitária - TFVS) can be covered. The corresponding fee is determined by Interministerial Ordinance N° 701, 31 August, 2015 or its updated versions.

More information about fees can be obtained through the link (only in Portuguese) <http://portal.anvisa.gov.br/taxas1>.

### How to follow the process

Progress of the request can be followed in SGAS system itself.

### How to know the result

After processing the payment, the notification of the product will be publicized on Anvisa's website through the link <http://cosmeticos.anvisa.gov.br/sgas/faces/relatorioExterno/consultaExterna.xhtml>. Hereafter, the product is authorized to be sold in Brazil.

The product must, necessarily, correspond to what was notified to Anvisa.

Anvisa may, at any time and in its discretion, require additional evidence or tests in case

that new events raise concerns about the product, even after granting its registration.

#### Validity of the process

Notification is valid for five years from the date of publication in Anvisa's website.

### **National Institute of Metrology, Quality and Technology – Inmetro**

Inmetro, through their Conformity Assessment Directorate, can regulate this scope if requested by Anvisa. Main information about Inmetro can be obtained at the website: <http://www.inmetro.gov.br>. Statement of weight and volume in pre-packaged products is also regulated by Inmetro, since it is a legal metrological requirement.

A list of documents published by Inmetro can be found in the Appendix I of this guide or can be viewed directly in the Inmetro database through the link [http://www.inmetro.gov.br/legislacao/consulta.asp?seq\\_classe=1&sig\\_classe=RTAC](http://www.inmetro.gov.br/legislacao/consulta.asp?seq_classe=1&sig_classe=RTAC).

### **Other authorities/relevant laws**

Internal Revenue Service (Customs) - Receita Federal (Aduana)

National Authority responsible for the control of import documents and taxes.

Website: <http://idg.receita.fazenda.gov.br>

The Chief of Staff of the Presidency of the Republic - Casa Civil da Presidência da República

The [Consumer Law](#) defines mandatory requirements applied to all commercial relation in Brazil.

### **Standards Developing Organization**

The Brazilian Official Standards responsible is the [ABNT](#) and a list of standards related to the scope can be found in the Appendix II of this guide or can be viewed directly in the ABNT database through the link <http://www.abntcatalogo.com.br>.

Note: Full text of Standards is not available for free.

## Testing laboratories

The conformity assessment process requires laboratories accredited by an ILAC member as Inmetro.

### ILAC Accredited Testing Laboratories

Inmetro is an ILAC member and the Brazilian official accreditation body. All the laboratories accredited by Inmetro are so according to ILAC criteria and has international recognition, according to the ILAC MRA, as explained in the footnote.

A list of accredited laboratories by Inmetro can be found in Appendix III or can be viewed directly in the Inmetro database through the link (only in Portuguese) <http://www.inmetro.gov.br/laboratorios/rble/>.

## Government stakeholders – contact information

### Brazilian Health Regulatory Agency

Agência Nacional de Vigilância Sanitária – ANVISA

Setor de Indústria e Abastecimento (SIA) - Trecho 5, Área Especial 57

71205-050 Brasília, DF, Brasil

Tel: + (55) 61 448.1078

Fax: + (55) 61 448.1089

E-mail: [rel@anvisa.gov.br](mailto:rel@anvisa.gov.br)

Website: <http://portal.anvisa.gov.br>

### Instituto Nacional de Metrologia, Qualidade e Tecnologia – INMETRO

Rua Santa Alexandrina, 416 - Rio Comprido

20.261-232 Rio de Janeiro, RJ, Brasil

Tel: + (55) 21 2563.2840

Fax: + (55) 21 2563.5637

Email: [barreirastecnicas@inmetro.gov.br](mailto:barreirastecnicas@inmetro.gov.br)

Website: <http://www.inmetro.gov.br/>

**Ministério da Indústria, Comércio e Serviços – MDIC**

Esplanada dos Ministérios, Bloco “J”,

70.053-900 Brasília, DF, Brasil

Tel: +55 (61) 2027-7000

Website: <http://www.mdic.gov.br/>

**Ministry of Justice and Citizenship – Ministério da Justiça e Cidadania**

Department of Consumer Protection - Departamento de Proteção e Defesa do Consumidor (DPDC)

Esplanada dos Ministérios, Bloco “T”, sala 520

70064-900 Brasília, DF, Brasil

Tel: +55 (61) 2025-3105

Website: <http://www.mj.gov.br/senacon>

**Associação Brasileira de Normas Técnicas – ABNT**

Rua Conselheiro Nébias, 1.131, Campos Elíseos

01203-002 São Paulo, SP, Brasil

Tel: +55 (11) 3017-3645/ 3646

Website: <http://www.abnt.org.br/>

## **Main Market Entity**

**Associação Brasileira da Indústria de Higiene Pessoal, Perfumaria e Cosméticos - ABIHPEC**

Av. Paulista, 1313, 10º andar, conjunto 1080, Bela Vista

01311-923 São Paulo, SP, Brasil

Tel: +55 (11) 3372-9899

Fax: + 55 (11) 3266-5387

Website: <https://www.abihpec.org.br/>



## Appendix I - Regulations

### Anvisa Regulations

**Law 6360/1976** - Regulates the health surveillance to which Medicines, Drugs, Pharmaceutical Drugs and Related, Cosmetics, Sanitizing and Other Products are subject and give other provisions.

**Decree 8077/2013** - Regulates the functioning conditions for companies subject to health licensing and regulates registration, control and monitoring, as part of health surveillance, of the products mentioned in Law 6360, of September 23, 1976, and other provisions.

**Law 6437/1977** - Establishes violations of federal health legislation, sanctions, and gives other provisions.

**Ordinance 295/1998** - Establishes criteria for inclusion, exclusion and concentration change of substances used in toiletries, cosmetics and perfumes.

**Ordinance 296/1998** - Provides that, for registration or change of registration purposes of toiletries, cosmetics and perfumes, in MERCOSUR, other nomenclatures should be adopted in a complementary manner to the original nomenclature of the formulation substances.

**Ordinance 344/1998** - Prohibited substances in Brazil.

**Resolution 481/1999** - Provides parameters for microbiological control of toiletries, cosmetics and perfumes.

**Resolution RDC 46/2002** - Technical Regulation for hydrated ethyl alcohol and anhydrous ethyl alcohol, marketed by wholesalers and Retailers.

**Resolution RDC 13/2003** - Provides for labeling to be included in oral hygiene products indicated for dentine hypersensitivity.

**Resolution RDC 13/2004** - Technical Regulation for Sanitary Surveillance of Entry, Consumption and Exit of the National Territory, of Goods Under Surveillance Sanitary services not regularized before the National Health Surveillance System, Exhibition, Demonstration or Distribution at Fairs or Events.

**Resolution 332/2005** - Provides that manufacturers and/or importers of Toiletries, Perfumes and Cosmetics Products companies installed in the country should implement a Cosmetic Vigilance System, as from December 31, 2005.

**Resolution RDC 176/2006** - Approves the Technical Regulation "Outsourcing hiring for toiletries, cosmetics and perfumes"

**Resolution RDC 42/2010** - Alcohol Products for Antiseptic Friction of Hands Indicated for Health Services

**Resolution RDC 3/2012** - Approves the Technical Regulation "Lists of substances that toiletries, cosmetics and perfumes products should not contain, except subject to the conditions and restrictions established" and other measures.

[Resolution RDC 29/2012](#) - Approves the MERCOSUR Technical Regulation about “List of substances with preservative action allowed for toiletries, cosmetics and perfumes” and other measures.

[Resolution RDC 30/2012](#) - Approves the MERCOSUR Technical Regulation about sunscreens in cosmetics and other measures.

[Resolution RDC 44/2012](#) - Approves the MERCOSUR Technical Regulation about “List of colorants permitted for toiletries, cosmetics and perfumes” and other measures.

[Resolution RDC 15/2013](#) - Approves the Technical Regulation about “List of substances for cosmetic use: lead acetate, pyrogallol, formaldehyde and paraformaldehyde”, and other measures.

[Resolution RDC 19/2013](#) - Provides technical requirements for registration concession of cosmetic insect repellent products , and other measures.

[Resolution RDC 48/2013](#) - Approves the Technical Regulation of Good Manufacturing Practices for toiletries, cosmetics and perfumes, and other measures.

[Resolution RDC 16/2014](#) - Criteria for petition of Authorization of the operation (AFE) and Special Authorization (EA) of Companies

[Resolution RDC 7/2015](#) - Provides for technical requirements for the regularization of toiletries, cosmetics and perfumes and other measures.

[Resolution RDC 15/2015](#) - Provides technical requirements for the concession of registration for children’s toiletries, cosmetics and perfumes, and other measures.

[Resolution RDC 35/2015](#) - Acceptance of alternative methods of animal experimentation recognized by the National Council for Control of Animal Experimentation - Conceal.

[Resolution RDC 69/2016](#) - Provides for “Technical Regulation MERCOSUR on ultraviolet filter list permitted for toiletries, cosmetics and perfumes”.

[Resolution RDC 83/2016](#) - Approves the MERCOSUR Technical Regulation about the list of substances that cannot be used in toiletries, cosmetics and perfumes.

[Resolution RDC 102/2016](#) - Transfer of product authorization ownership

[Resolution RDC 126/2016](#) - Provides on the definition and technical requirements of cosmetics related to skin bronze and establish labeling warning for bronze activators / accelerators.

[Resolution RDC 131/2016](#) - Provides the inclusion of a warning phrase in the labeling of personal hygiene products, cosmetics and perfumes intended for governmental programs linked to the Unified Health System (SUS).

[Resolution RDC 142/2017](#) - Provides for the regularization of disposable personal hygiene products intended for body cleanliness, which include toothbrushes and rods for oral hygiene, dental floss and tapes, disposable absorbents, menstrual cups and cotton swabs.

## Inmetro Regulations

**Ordinance 330/2006** - Provide the proposed text of MERCOSUR Draft Resolution, attached, to approve the MERCOSUR Technical Regulation on quantitative indication of cosmetics.

**Ordinance 115/2001** - For prepackaged cosmetics and toiletries, marketed in units of mass or volume, whose nominal content is between 5g and 20g, or 5ml and 20ml, the batch approval criteria set out in item 5.1 of the Metrological Technical Regulation approved by INMETRO No. 74 of May 25, 1995, does not apply.

**Decree 69/2001** - The cosmetic, personal hygiene and grooming products, which are present in solid, semisolid, gel, a mixture of solid and liquid, and which are physically characterized by the absence of flow, should have its quantitative indication expressed in mass legal units, their multiples and submultiples.

## Appendix II - Standards

ABNT standards can be purchased at <http://www.abnt.org.br/adquira-sua-norma>.

ABNT NBR 16160: 2013 - This standard establishes the minimum requirements for aluminum tubes used in cosmetic industries, including definitions, receiving conditions and test methods.

ABNT NBR 16276: 2016 - This standard establishes the requirements and test methods for safety protective creams used against chemical agents.

ABNT NBR ISO 21149: 2008 - This standard provides a general guide for the enumeration and detection of aerobic mesophilic bacteria.

ABNT NBR ISO 21150: 2008 - This standard provides a general guide for detection and identification of microorganism *Escherichia coli* in cosmetic products.

ABNT NBR ISO 22717: 2008 - This standard provides a general guide for detection and identification of microorganism *Pseudomonas aeruginosa* in cosmetic products.

ISO 22718: 2008 - This standard provides a general guide for detection and identification of microorganism *Staphylococcus aureus* in cosmetic products.

## Appendix III - Testing Laboratories relevant to the Scope

### Testing laboratories accredited by ILAC member (Inmetro)

#### **Plantec P.T.A. Ltda**

Rodovia SP 147, km 128 – Iracemópolis/SP

Tel: (19) 3112-0612 (19) 98151-9338

e-mail: alexandre.santos@planteclab.com

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=PLANTEC%2F17025](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=PLANTEC%2F17025)

#### **Fundação Ezequiel Dias**

Rua Conde Pereira Carneiro, 80 – Belo Horizonte/MG

Tel: (31) 3314-4700/4701

E-mail: adriane@funed.mg.gov.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=FUNED](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=FUNED)

#### **Ortofarma Laboratório de Controle da Qualidade Ltda**

BR 040 prox km 800 Empresarial Park Sul – Matias Barbosa/MG

Tel: (32) 3273.3560

E-mail: ortofarma@ortofarma.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=ORTOFARMA](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=ORTOFARMA)

#### **Laboratório Analítico Farmacêutico Ltda**

Rua T29, 1.006 –Bueno – Goiania/GO

Tel: (62) 3252.1931

E-mail: lafarmcqm@gmail.com

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=LAFARM](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=LAFARM)

#### **TUV SUD SFDK Laboratório de Análise de Produtos Ltda**

Avenida Aratãs, 754 – Moema – São Paulo/SP

Tel: (11) 5097.7888

E-mail: daniel.bhering@tuv-sud.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=SFDK](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=SFDK)

**Faculdade de Ciências Farmacêuticas da Universidade de São Paulo - FCF/USP/CONFAR**

Avenida Professor Lineu Prestes - 580 - Bl. 13 A – Cidade Universitária – São Paulo/SP

Tel: (11) 3091.3626 e 3091.2218

E-mail: roryama@usp.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=USP%2FCONFAR](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=USP%2FCONFAR)

**Instituto Nacional de Controle de Qualidade em Saude da Fiocruz - Fundação Oswaldo Cruz**

Av. Brasil, 4.365 – Manguinhos – Rio de Janeiro/RJ

Tel: (021) 3865.5104

E-mail: vdquali@incqs.fiocruz.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=INCQS%2DFIOCRUZ](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=INCQS%2DFIOCRUZ)

**Bioagri Laboratórios Ltda.**

Rodovia SP 127 - km 24 – Guamium – Piracicaba/SP

Tel: (19) 3429.7754 / 3429.7733

E-mail: celso.zaccaria@mxns.com

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=BIOAGRI%2FLAR](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=BIOAGRI%2FLAR)

**Bioagri Laboratórios Ltda.**

Via Vicente Verti, 655 e 835 - Bela Vista – Charqueada/SP

Tel: (19) 3486.0999

E-mail: celso.zaccaria@mxns.com

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=BIOAGRI+CHARQUEADA](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=BIOAGRI+CHARQUEADA)

**Cetal S/S Ltda.**

Rua Tenente Onofre Rodrigues de Aguiar, 740 – Vila Industrial – Mogi das Cruzes/SP

Tel: (11) 4699.2001

E-mail: adriana@cetal.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=CETAL%2DMOGI](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=CETAL%2DMOGI)

**NSF Bioensaios - Prestação de Serviços de Análises e Certificação Ltda.**

Rua Palermo, 257 – Santa Isabel – Viamão/RS

Tel: (51) 3493.6888

E-mail: epritsch@nsf.org

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=BIOENSAIOS17025](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=BIOENSAIOS17025)

**Conágua Ambiental Ltda.**

Rua 91, 771 – Setor Sul – Goiânia/GO

Tel: (62) 3218.1010

E-mail: [qualidade@conaguaambiental.com.br](mailto:qualidade@conaguaambiental.com.br)

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=CONAGUA](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=CONAGUA)

**A3Q Laboratório Ltda.**

Rua Uruguai, 533 – Alto Alegre – Cascavel/PR

Tel: (45) 3333-6000

E-mail: [gerente.micro@a3q.com.br](mailto:gerente.micro@a3q.com.br)

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=A3Q](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=A3Q)

**Centro de Qualidade Analítica Ltda.**

Avenida Júlio Diniz, 27 - Jd. Nossa Sra Auxiliadora – Campinas/SP

Tel: (19) 3241-1555

E-mail: [marcelo@cqa.com.br](mailto:marcelo@cqa.com.br)

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=CQA](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=CQA)

**Cascardi Saneamento Básico Ltda.**

Rua Guaira, 132 - Jardim Barbosa – Guarulhos/SP

Tel: (11) 2408.3283

E-mail: [cascardi@cascardi.com.br](mailto:cascardi@cascardi.com.br)

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=CASCARDI](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=CASCARDI)

**Labor Três Laboratórios e Consultoria Técnica Ltda.**

Avenida Damasceno Vieira, 542 – Vila mascote – São Paulo/SP

Tel: (11) 5678.2333

E-mail: [andreanehme@labor3.com.br](mailto:andreanehme@labor3.com.br)

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=LABOR+TR%2DCAS](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=LABOR+TR%2DCAS)

**Tecam Tecnologia Ambiental Ltda.**

Rua Fábica, 59 – Vila Romana – São Paulo/SP

Tel: (11) 3677.2553

E-mail: [janete.moura@tecam.com.br](mailto:janete.moura@tecam.com.br)

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=TECAM%2D17025](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=TECAM%2D17025)

**LASA Pesquisas Laboratoriais Ltda. / Dosage**

Av. Dr. Romeu Tórtima, 739 - Cidade Universitária – Campinas/SP

Tel: (19) 3789.8600

E-mail: samuel@grupoinvestiga.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=LASA](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=LASA)

**AMBIOTEC Laboratório de Tecnologia Ambiental Eireli**

Rua São Carlos, 11 - Jardim das Indústrias - São José dos Campos/SP

Tel: (12) 3934.4935

E-mail: marcosjacomassi@ambiotecclab.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=AMBIOTEC](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=AMBIOTEC)

**T&E Analítica Comércio e Análises Químicas Ltda.**

Rua Lauro Vannucci, 1.260 - Jardim Santa Cândida – Campinas/SP

Tel: (19) 3756.6600

E-mail: flavio@teanalitica.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=T%26E+ANALITICA](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=T%26E+ANALITICA)

**LS Analyses Laboratório de Pesquisas e Análises Químicas, Físico-Químicas e Microbiológicas Ltda.**

Rua Salvador de Sá, 112 - Santa Terezinha - Santo André/SP

Tel: (11) 4996.1947

E-mail: lais@lsanalyses.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=LS+ANALYSES](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=LS+ANALYSES)

**Controlbio Assessoria Técnica Microbiológica S/S Ltda.**

Rua Comendador Elias Assi, 645 - Jd. Caxingui – São Paulo/SP

Tel: (11) 3721.7760

E-mail: controlbio@controlbio.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=CONTROLBIO](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=CONTROLBIO)

**PróLab Laboratório de Biotecnologia S/S Ltda.**

Rua Ângelo Maglio, 65 - Vila Yara – Osasco/SP

Tel: (11) 3685.4003

E-mail: elianebravo@prolabnet.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=PRO%2DLAB](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=PRO%2DLAB)



**Laboratórios Ecolyzer Ltda.**

Rua Romão Puiggari, 898 - Vila das Mercês – São Paulo/SP

Tel: (11) 2969.5020

E-mail: glaucio@ecolyzer.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=ECOLYZER%2FMERCES](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=ECOLYZER%2FMERCES)

**Laboratórios Ecolyzer Ltda.**

Rua Sebastiano Mazzoni, 263- Vila Moraes – São Paulo/SP

Tel: (11) 2969.5020

E-mail: glaucio@ecolyzer.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=ECOLYZER%2FMERCES](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=ECOLYZER%2FMERCES)

**BCQ Consultoria e Qualidade Sociedade Simples Ltda.**

Rua Conde Moreira Lima, 589 - Jardim Jabaquara – São Paulo/SP

Tel: (11) 5539.6710

E-mail: tecnica@bcq.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=BCQ](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=BCQ)

**Allergisa Pesquisa Dermato Cosmética Ltda.**

Avenida Dr. Romeu Tórtima, 739 - Cidade Universitária – Campinas/SP

Tel: (19) 3517-6840

E-mail: lucas@grupoinvestiga.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=ALLERGISA](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=ALLERGISA)

**Instituto Adolfo Lutz**

Av. Dr. Srnaldo, 355 - Cerqueira César – São Paulo/SP

Tel: (11) 3068-2852

E-mail: expedientedg@ial.sp.gov.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=IAL](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=IAL)

**MEDLAB Produtos Diagnósticos Ltda.**

Rua Octavio Teixeira Mendes Sobrinho, 35 - Vila Santa Catarina – São Paulo/SP

Tel: (11) 5671.7664

E-mail: gabriela.korek@medlab.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=MEDLAB](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=MEDLAB)

**Instituto Terapêutico Delta Ltda.**

Estrada Capovilla ,129 - Recreio Campestre – Indaiatuba/SP

Tel: (19) 3801.8900

E-mail: fernanda.colosimo@labdelta.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=DELTA](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=DELTA)

**Fundação Vale do Taquari de Educação e Desenvolvimento Social – FUVATES**

Rua Avelino Tallini, 171 – Bairro Universitário – Lajeado/RS

Tel: (51) 3714.7027

E-mail: labfq@univates.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=FUVATES](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=FUVATES)

**Avisa Serviços Técnicos em Vigilância Sanitária, Tecnologia e Meio Ambiente Ltda.**

Rua José Maria Lisboa, 275 – jardim Paulista – São Paulo/SP

Tel: (11) 3884.5901

E-mail: microbiologico@avisa.srv.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=AVISA](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=AVISA)

**Guzen & Guzen Ltda.**

Rua Salvador, 29 – Centro - Ouro Verde do Oeste/PR

Tel: (45) 3251.1036

E-mail: karla@elementum.far.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=GUZEN](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=GUZEN)

**JBS S/A**

Rodovia BR 153, km 179 - Bloco 2 – Zona Rural – Lins/SP

Tel: (14) 3533.2160

E-mail: andressa.galletti@lin.jbs.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=JBS%2FHIGIENE](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=JBS%2FHIGIENE)

**Analítica: Análises Físico-químicas e Microbiológicas Ltda.**

Giovanni Baptista Raffo, 120 – Raffo – Suzano/SP

Tel: (11) 4748.2730

E-mail: analitica@analiticalab.com.br

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**Biocientific Laboratórios Ltda.**

Avenida Desembargador Hugo Simas ,1215/Conj 08 – Vista Alegre – Curitiba/PR

Tel: (41) 3338.8562

E-mail: keise@biocientific.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=BIOCIENTIFIC](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=BIOCIENTIFIC)

**Pasteur Laboratório de Pesquisa e Controle de Qualidade Microbiológico Ltda.**

Rua General Câmara, 1.000 – Centro - Sta Bárbara D'Oeste/SP

Tel: (19) 3455.1382

E-mail: gisleine.santos@pasteurcontrol.com.br

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=PASTEUR](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=PASTEUR)

**Kosmoscience Ciência e Tecnologia Cosmética, Importação e Exportação Ltda.**

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Tel: (19) 3829.3482

E-mail: fernandagoncalves@kosmoscience.com

[http://www.inmetro.gov.br/laboratorios/rble/detalhe\\_laboratorio.asp?nom\\_apelido=KOSMOSCIENCE](http://www.inmetro.gov.br/laboratorios/rble/detalhe_laboratorio.asp?nom_apelido=KOSMOSCIENCE)



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