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OFFICIAL FEDERAL GAZETTE

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Body: Ministry of Health/National Health Surveillance Agency/Collegiate Board of Directors

RDC RESOLUTION - No. 743, OF AUGUST 10, 2022

Establishes the risk classification and deadlines for responding to the requirements of public acts of release of liability from Anvisa, as provided for in the caput of Art. 3 and Art. 10 of Decree No. 10.178, of December 18, 2019

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the powers conferred upon it by Art. 15, III and IV, allied to Art. 7, III and IV of Law No. 9,782, of January 26, 1999, and to Art. 187, VI,

§ 1 of the Internal Regulations approved by Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, hereby decides to adopt the following Resolution, as resolved at a meeting held on August 9, 2022, and I, the Chief Executive Officer, hereby determine its publication.

Art. 1 This Resolution establishes the risk classification and deadlines for responding to the requirements of public acts of release of liability from Anvisa, as provided for in the caput of Art. 3 and Art. 10 of Decree No. 10.178, of December 18, 2019

Art. 2 The risk classification and the corresponding deadlines for responding to the requirements of public acts of release of liability from Anvisa shall be observed, as established in the Annex to this Resolution.

Sole Paragraph. The lack of a conclusive statement regarding the approval of public acts of release of liability from Anvisa shall imply its tacit approval, except in the cases provided for in the Annex to this Resolution.

Art. 3 RDC No. 416 of August 27, 2020, published in the DOU No. 167, of August 31, 2020, Section 1, page 135, is hereby revoked.

Art. 4 This Resolution enters into force on September 1, 2022.

ANTONIO BARRA TORRES
Chief Executive Officer

ANNEX

PUBLIC ACT OF RELEASE - HEALTH PRODUCTS - CLINICAL TRIALS	DELETED TEXT		
EQUIPMENT - Amendment of notification of class I - Immediate implementation	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
EQUIPMENT - Amendment of notification of class II - Immediate implementation	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
EQUIPMENT - Amendment of notification of class I or II Medical Software - Immediate implementation - new indications and functionalities or change of the visual identity of the software	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
EQUIPMENT - Amendment of registration - Required approval - Addition of equipment to a family of large-sized equipment	**RISK III**	**Tacit approval does not apply**	**150 days**
EQUIPMENT - Amendment of registration - Required approval - Addition of equipment to a family of small- and medium-sized equipment	**RISK III**	**Tacit approval does not apply**	**150 days**

EQUIPMENT - Amendment of registration - Required approval - Software change (new indications and features)	**RISK III**	**Tacit approval does not apply**	**150 days**
EQUIPMENT - Amendment of registration - Required approval - Technical change	**RISK III**	**Tacit approval does not apply**	**150 days**
EQUIPMENT - Amendment of registration - Required approval - Change/inclusion of indication and purpose of use, type of operator or patient or environment of use	**RISK III**	**Tacit approval does not apply**	**150 days**
EQUIPMENT - Amendment of registration - Required approval - Change/inclusion of components in the system	**RISK III**	**Tacit approval does not apply**	**150 days**
EQUIPMENT - Amendment of registration - Required approval - Change/inclusion of manufacturing site (manufacturing unit)	**RISK III**	**Tacit approval does not apply**	**150 days**
EQUIPMENT - Amendment of registration - Required approval - Change/inclusion of sterilization or reprocessing method and expiration	**RISK III**	**Tacit approval does not apply**	**150 days**
EQUIPMENT - Amendment of registration - Required approval - Change/inclusion of parts and accessories	**RISK III**	**Tacit approval does not apply**	**150 days**
EQUIPMENT - Registration changes - Immediate implementation - Change of the commercial name and/or denomination of the name/code (part number) of the commercial model, component, part or accessory; or the visual identity of the software	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
EQUIPMENT - Registration changes - Immediate implementation - Change/inclusion/exclusion of legal manufacturer, without changing the manufacturing process; and/or exclusion of a manufacturing unit	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
EQUIPMENT - Registration changes - Immediate implementation - Storage, transport and operation conditions	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**

EQUIPMENT - Registration changes - Immediate implementation - Contraindications, adverse effects, warnings or precautions	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
EQUIPMENT - Registration changes - Immediate implementation - Exclusion of models, system components, accessories, parts, indication of use, sterilization method	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
EQUIPMENT - Amendment of registration - Immediate implementation - Trade name of the foreign legal manufacturer or manufacturing unit	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
EQUIPMENT - Cancellation of registration or notification upon request of the company	**RISK II**	**Tacit approval does not apply**	**30 days**
EQUIPMENT - Cancellation of registration due to transfer of ownership	**RISK II**	**Tacit approval does not apply**	**30 days**
EQUIPMENT - Notification of Class I Medical Device	**RISK II**	**Tacit approval does not apply**	**30 days**
EQUIPMENT - Notification of Class II Medical Device	**RISK II**	**Tacit approval does not apply**	**30 days**
EQUIPMENT - Notification of Class I or II Medical Software	**RISK II**	**Tacit approval does not apply**	**30 days**
EQUIPMENT - Registration of Large-sized Health Equipment	**RISK III**	**Tacit approval does not apply**	**250 days**
EQUIPMENT - Registration of Small- and Medium-sized Health Equipment	**RISK III**	**Tacit approval does not apply**	**250 days**
EQUIPMENT - Registration of Family of Large-sized Health Equipment	**RISK III**	**Tacit approval does not apply**	**250 days**
EQUIPMENT - Registration of Family of Small- and Medium-sized Health Equipment	**RISK III**	**Tacit approval does not apply**	**250 days**
EQUIPMENT - Registration of Family of Medical Software	**RISK III**	**Tacit approval does not apply**	**250 days**
EQUIPMENT - Registration of System of Large-sized Health Equipment	**RISK III**	**Tacit approval does not apply**	**250 days**
EQUIPMENT - Registration of System of Small- and Medium-sized Health Equipment	**RISK III**	**Tacit approval does not apply**	**250 days**
EQUIPMENT - Registration of Medical Software	**RISK III**	**Tacit approval does not apply**	**250 days**
EQUIPMENT - Rectification - Correction by ANVISA	**RISK III**	**Tacit approval does not apply**	**60 days**
EQUIPMENT - Rectification - Correction by COMPANY	**RISK III**	**Tacit approval does not apply**	**60 days**
EQUIPMENT - Revalidation of Registration of Large-sized Equipment	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
EQUIPMENT - Revalidation of Registration of Small and Medium-sized Equipment	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**

EQUIPMENT - Revalidation of Registration of System/Family of Large-sized Equipment	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
EQUIPMENT - Revalidation of Registration of System/Family of Small- and Medium-sized Equipment	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
EQUIPMENT - Transfer of product registration ownership	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Amendment of notification - Immediate implementation	**RISK III**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
MATERIAL - Amendment of registration - Required approval - Addition of material in family	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Amendment of registration - Required approval - Change of technical dossier information	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Amendment of registration - Required approval - Change/inclusion of commercial presentation	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Amendment of registration - Required Approval - Change/inclusion of indication of use, mode of use, contraindications, adverse events, warnings or precautions	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Amendment of registration - Required approval - Change/inclusion of the sterilization method	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Amendment of registration - Required approval - Chemical composition/raw material	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Amendment of registration - Required Approval - Inclusion/change of accessories of exclusive use in the registration of family	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Amendment of registration - Required approval - Manufacturing site - Inclusion or change of manufacturing unit	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Amendment of registration - Required approval - Product expiration date and/or Product storage or transport conditions	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Amendment of registration - Immediate implementation - Change only of the commercial name and/or denomination of the name/code of the commercial model, system component, part or accessory of the product	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
MATERIAL - Amendment of registration - Immediate implementation - Change/inclusion/exclusion of legal manufacturer, without changing the manufacturing process; and/or exclusion of a manufacturing unit	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 2020**	**30 days**
MATERIAL - Amendment of registration - Immediate implementation - Exclusion of models, commercial presentations, components, accessories; exclusion of indication of use; exclusion of sterilization method	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 2020**	**30 days**

MATERIAL - Amendment of registration - Immediate implementation - Trade name of the foreign legal manufacturer or manufacturing unit	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
MATERIAL - Consent to manufacture or import custom-made medical devices	**RISK III**	**Tacit approval does not apply**	**90 days**
MATERIAL - Cancellation of registration or notification upon request of the company	**RISK II**	**Tacit approval does not apply**	**30 days**
MATERIAL - Cancellation of registration due to transfer of ownership	**RISK II**	**Tacit approval does not apply**	**30 days**
MATERIAL - Notification of Class I Medical Device	**RISK II**	**Tacit approval does not apply**	**30 days**
MATERIAL - Notification of Class II Medical Device	**RISK II**	**Tacit approval does not apply**	**30 days**
MATERIAL - Notification of manufacture or import of custom-made medical device (Classes III and IV)	**RISK II**	**Tacit approval does not apply**	**N/A**
MATERIAL - Registration of Set of Materials for Medical Use	**RISK III**	**Tacit approval does not apply**	**320 days**
MATERIAL - Registration of Family of Implant Material in Orthopedics	**RISK III**	**Tacit approval does not apply**	**320 days**
MATERIAL - Registration of Family of Material for Medical Use	**RISK III**	**Tacit approval does not apply**	**320 days**
MATERIAL - Registration of Material for Medical Use	**RISK III**	**Tacit approval does not apply**	**320 days**
MATERIAL - Registration of Implant Material in Orthopedics	**RISK III**	**Tacit approval does not apply**	**320 days**
MATERIAL - Registration of System of Material for Medical Use	**RISK III**	**Tacit approval does not apply**	**320 days**
MATERIAL - Registration of System of Implant Material in Orthopedics	**RISK III**	**Tacit approval does not apply**	**320 days**
MATERIAL - Rectification - Correction by ANVISA	**RISK III**	**Tacit approval does not apply**	**60 days**
MATERIAL - Rectification - Correction by COMPANY	**RISK III**	**Tacit approval does not apply**	**60 days**
MATERIAL - Revalidation of Registration	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
MATERIAL - Revalidation of Registration of Set	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
MATERIAL - Revalidation of Registration of Family	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**

MATERIAL - Revalidation of registration of family of implant material in orthopedics	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
MATERIAL - Revalidation of registration of implant material in orthopedics	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
MATERIAL - Revalidation of Registration of SYSTEM	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
MATERIAL - Revalidation of registration of system of implant material in orthopedics	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
MATERIAL - Transfer of ownership of registration of material for health use	**RISK III**	**Tacit approval does not apply**	**150 days**
MATERIAL - Transfer of ownership of registration of implant material in orthopedics	**RISK III**	**Tacit approval does not apply**	**150 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Required approval - Addition of model in family	**RISK III**	**Tacit approval does not apply**	**150 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Required approval - Change of technical dossier information	**RISK III**	**Tacit approval does not apply**	**150 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Required approval - Change/inclusion of indication of use, mode of use, contraindications, adverse events, warnings and/or precautions	**RISK III**	**Tacit approval does not apply**	**150 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Required approval - Change/inclusion of commercial presentation	**RISK III**	**Tacit approval does not apply**	**150 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Required approval - Change/inclusion of component/accessory in the system	**RISK III**	**Tacit approval does not apply**	**150 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Required approval - Change/inclusion of the sterilization method	**RISK III**	**Tacit approval does not apply**	**150 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Required approval - Chemical composition/raw material	**RISK III**	**Tacit approval does not apply**	**150 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Required approval - Manufacturing site - Inclusion or change of manufacturing unit	**RISK III**	**Tacit approval does not apply**	**150 days**
ORTHOPEDICS MATERIAL - Amendment of registration - Required approval - Product expiration date and/or storage and/or transport conditions	**RISK III**	**Tacit approval does not apply**	**150 days**

ORTHOPEDIC MATERIAL - Amendment of registration - Immediate implementation - Change only of the commercial name and/or denomination of the name/code of the commercial model, system component, part or accessory of the product	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Immediate implementation - Change/inclusion/exclusion of legal manufacturer, without changing the manufacturing process; and/or exclusion of a manufacturing unit	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Immediate implementation - Exclusion of models, commercial presentations, components, accessories; exclusion of indication of use; exclusion of sterilization method	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
ORTHOPEDIC MATERIAL - Amendment of registration - Immediate implementation - Trade name of the foreign legal manufacturer or manufacturing unit	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
IVD - Amendment of notification - Immediate implementation.	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
IVD - Amendment of registration - Required approval - Composition of products or instrument models	**RISK III**	**Tacit approval does not apply**	**150 days**
IVD - Amendment of registration - Required approval - Inclusion of the manufacturing site (manufacturing unit)	**RISK III**	**Tacit approval does not apply**	**150 days**
IVD - Amendment of registration - Required approval - Inclusion of the product in family	**RISK III**	**Tacit approval does not apply**	**150 days**
IVD - Amendment of registration - Required approval - Information from the technical product dossier: indication of use or intended use; instructions for use (except interferences and limitations); biological samples; analytical performance (except interferences and limitations); stability; conservation and expiration date; clinical performance; manufacturing process	**RISK III**	**Tacit approval does not apply**	**150 days**
IVD - Amendment of registration - Immediate implementation - Commercial presentation of products or instrument parts and accessories	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
IVD - Amendment of registration - Immediate implementation - Exclusion of product in family	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**
IVD - Amendment of registration - Immediate implementation - Legal manufacturer of the product, without changing the manufacturing process.	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 6, 2020**	**30 days**

IVD - Amendment of registration - Immediate implementation - Interferences and limitations	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 2020**	**30 days**
IVD - Amendment of registration - Immediate implementation - Commercial name of the product	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 2020**	**30 days**
IVD - Amendment of registration - Immediate implementation - Trade name of the foreign legal manufacturer or manufacturing unit	**RISK II**	**Tacit approval pursuant to Art. 9 of the Resolution of the Collegiate Board of Directors - RDC No. 340, of March 2020**	**30 days**
IVD - Exceptional consent for retroactive application of expiration date extension	**RISK III**	**Tacit approval does not apply**	**150 days**
IVD - Notification of Class I product	**RISK II**	**Tacit approval does not apply**	**30 days**
IVD - Notification of Class II product	**RISK II**	**Tacit approval does not apply**	**30 days**
IVD - Notification of imported products in Class II family	**RISK II**	**Tacit approval does not apply**	**30 days**
IVD - Notification of national products in Class II family	**RISK II**	**Tacit approval does not apply**	**30 days**
IVD - Cancellation of registration or notification upon request of the company	**RISK II**	**Tacit approval does not apply**	**30 days**
IVD - Cancellation of registration due to transfer of ownership	**RISK II**	**Tacit approval does not apply**	**30 days**
IVD - Registration of product	**RISK III**	**Tacit approval does not apply**	**365 days**
IVD - Registration of imported products in family	**RISK III**	**Tacit approval does not apply**	**365 days**
IVD - Registration of national products in family	**RISK III**	**Tacit approval does not apply**	**365 days**
IVD - Rectification - Correction by ANVISA	**RISK III**	**Tacit approval does not apply**	**60 days**
IVD - Rectification - Correction by COMPANY	**RISK III**	**Tacit approval does not apply**	**60 days**
IVD - Revalidation of Registration	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
IVD - Revalidation of registration in family	**RISK III**	**Tacit approval pursuant to Art. 12, § 6 and Art. 17-A, § 3 of Law No. 6.360 of September 23, 1976, and Art. 1 of RDC No. 250 of October 20, 2004**	**180 days**
IVD - Transfer of ownership of registration of family of products	**RISK III**	**Tacit approval does not apply**	**150 days**
IVD - Transfer of ownership of registration of product	**RISK III**	**Tacit approval does not apply**	**150 days**

PUBLIC ACT OF RELEASE - TOXICOLOGICAL ASSESSMENT	**DELETED TEXT**		
PUBLIC ACT OF RELEASE - TOBACCO-DERIVED SMOKING PRODUCTS	**DELETED TEXT**		
PUBLIC ACT OF RELEASE - FOOD	**DELETED TEXT**		
PUBLIC ACT OF RELEASE - PERSONAL HYGIENE PRODUCTS, COSMETICS AND PERFUMES	**DELETED TEXT**		
PUBLIC ACT OF RELEASE - SANITIZING PRODUCTS	**DELETED TEXT**		
PUBLIC ACT OF RELEASE - DRUGS	**DELETED TEXT**		
PUBLIC ACT OF RELEASE - MONITORING ASSESSMENT	**DELETED TEXT**		
HEALTH PRODUCTS - Consent to Run Advertising Containing Alert to the Population, within the Term and Conditions Indicated by the Health Authority	**RISK III**	**Tacit approval does not apply**	**30 days**

PUBLIC ACT OF RELEASE - BLOOD, TISSUES, CELLS, ORGANS, and ADVANCED THERAPY PRODUCTS	**DELETED TEXT**		

PUBLIC ACT OF RELEASE - PORTS, AIRPORTS AND BORDERS HEALTH PRODUCTS	RISK CLASSIFICATION	PREDICTABILITY	DEADLINE
Amendments in the Company Operating Permit (AFE), Special Permit (AE), or Registration of branch of company holding an Operating Permit	**RISK II**	**Tacit approval does not apply**	**60 days**
Company Operating Permit (AFE) of company that provides support point services of land vehicle that operates international collective transport of passengers	**RISK II**	**Tacit approval does not apply**	**60 days**

Company Operating Permit (AFE) of company that provides import services of cosmetics, hygiene products, sanitizing products, health products and drugs on behalf of a third party or by means of order.	RISK II	Tacit approval does not apply	60 days
Company Operating Permit (AFE) of company that provides cleaning and collection services of waste resulting from the treatment of wastewater and waste in port and airport terminals for cargo and travelers, customs terminals for public use, stations, and border crossings	RISK II	Tacit approval does not apply	60 days
Company Operating Permit (AFE) of company that provide services of hospitality, beauty institutes and counterparts; laundry, medical care, or sale of medical-hospital materials and equipment in port areas, airports, and border crossing points	RISK II	Tacit approval does not apply	60 days
Company Operating Permit (AFE) of company that provides business administration or representation services, on behalf of the legal representative or person directly responsible for the vessel, taking the necessary measures for its dispatch in organized ports and waterway terminals installed in the national territory	RISK II	Tacit approval does not apply	60 days
Registration of branch of company holding an Operating Permit	RISK II	Tacit approval does not apply	60 days
Cancellation of the Company Operating Permit (AFE), Special Permit (AE), or Registration of branch of company holding an Operating Permit	RISK II	Tacit approval does not apply	60 days
Communication of start of activities of company that provides services of public health interest in land vehicles that operate international collective transport of passengers, vessels, aircraft, waterway terminals, organized ports, airports, border stations, and bonded warehouses	RISK II	Tacit approval does not apply	60 days
Application for the issuance of a Certificate and 2nd copy of a Certificate of Company Operating Permit (AFE) or Special Permit (AE) - Except Pharmacies and Drugstores	RISK II	Tacit approval does not apply	60 days
Rectification of Publication	RISK II	Tacit approval does not apply	60 days
Company Operating Permit (AFE) and Special Permit (AE) of company that provides storage services for food, cosmetics, hygiene products, drugs, health products, sanitizers, controlled substances and drugs containing them, in bonded warehouses.	RISK III	Tacit approval does not apply	60 days
Company Operating Permit (AFE) of company that provides supply services of drinking water for human consumption on-board of Aircraft, Vessels, and Land Vehicles that operate international collective transport of passengers	RISK III	Tacit approval does not apply	60 days
Company Operating Permit (AFE) of company that provides sewage and treatment services of health wastewater from Aircraft, Vessels, and Land Vehicles in transit through border crossings and stations at airport and port terminals and border crossings and stations	RISK III	Tacit approval does not apply	60 days
Company Operating Permit (AFE) of company that provides segregation, collection, packaging, storage, transport, treatment, and final disposal services of solid waste resulting from Aircraft, Land Vehicles in transit through border crossings and stations, Vessels, port and airport terminals for cargo and travelers, bonded terminals for public use and border crossings and stations	RISK III	Tacit approval does not apply	60 days
Company Operating Permit (AFE) of company that provides disinsection or extermination of rat services on Vessels, Land Vehicles in transit through border crossings and stations, Aircraft, port and airport terminals for cargo and travelers, bonded terminals for public use and border crossings and stations	RISK III	Tacit approval does not apply	60 days

Company Operating Permit (AFE) of company that provides cleaning, disinfection and decontamination services for the surfaces of Aircraft, Land Vehicles in transit through border crossings and stations, Vessels, port and airport terminals for cargo and travelers, bonded terminals for public use and border crossings and stations	**RISK III**	**Tacit approval does not apply**	**60 days**
Certification of Good Storage Practices for DRUGS, PHARMACEUTICAL INGREDIENTS and HEALTH PRODUCTS	**RISK III**	**Tacit approval does not apply**	**365 days**
CRUISE VESSEL - Addendum	**RISK III**	**Tacit approval does not apply**	**72 hours**
CRUISE VESSEL - Submission of documentation	**RISK III**	**Tacit approval does not apply**	**72 hours**
Issuance of on-board health control certificate or exemption from on-board health control for vessels	**RISK III**	**Tacit approval does not apply**	**72 hours**
Issuance of a certificate of free practice for vessels that perform long-distance or inland navigation in international transit	**RISK III**	**Tacit approval does not apply**	**72 hours**
Semi-annual Inspection of Platforms for the issuance of Health Certificate	**RISK III**	**Tacit approval does not apply**	**60 days**

IMPORT LICENSING	RISK CLASSIFICATION	PREDICTABILITY	DEADLINES
Health Inspection of drugs and substances subject to special control	**Deleted text**		
Health Inspection of health products, part of procedure 4, imported by a legal entity for industrial or commercial purposes	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of HOUSEHOLD SANITIZING PRODUCTS	**DELETED TEXT**		
Health Inspection of in vitro diagnostic products and raw materials that compose them, part of procedure 5.5, imported by a legal entity for industrial or commercial purposes	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of food,	**DELETED TEXT**		
Health Inspection of part of procedure 5.1, imported by a legal entity for industrial or commercial purposes	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of items whose starting material is tissues/fluids from ruminant animals, part of procedure 6, by a legal entity for industrial or commercial purposes, category I, II, III	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of product samples (except drugs), not regularized at Anvisa, intended for Quality Control tests, packaging and labeling assessment, equipment tests, or new product development	**RISK III**	**Tacit approval does not apply**	**60 days**

Health Inspection of product samples (except drugs), or raw materials that are part of them, for purposes of analysis and experiences related to registration approval	RISK III	Tacit approval does not apply	60 days
Health Inspection of drug samples, not regularized at ANVISA, or raw materials that are part of them, for purposes of analysis and experience, intended for REGISTRATION APPROVAL	RISK III	Tacit approval does not apply	60 days
Health Inspection of drug samples, finished product, not regularized at ANVISA, intended for QUALITY CONTROL	RISK III	Tacit approval does not apply	60 days
Health Inspection of samples of food, cosmetics, hygiene products and perfumes or household sanitizing products, not regularized at ANVISA, intended for Market Research	RISK III	Tacit approval does not apply	60 days
Health Inspection of drug samples, not regularized at ANVISA, intended for EQUIPMENT OPERATIONAL PHASE TESTING that are part of the manufacturing or laboratory process	RISK III	Tacit approval does not apply	60 days
Health Inspection of an international DONATION of goods under health surveillance	RISK III	Tacit approval does not apply	60 days
Health Inspection of drug samples under Clinical Research	RISK III	Tacit approval does not apply	60 days
Health inspection of medical products under Clinical Research	RISK III	Tacit approval does not apply	60 days
Health Inspection of food, cosmetics, hygiene products and perfume, health products or in vitro diagnostic products, intended for Clinical Research	RISK III	Tacit approval does not apply	60 days
Health Inspection of biological material collection kit for Clinical Research assessment	RISK III	Tacit approval does not apply	60 days
Health Inspection of goods under health surveillance for initial supply or substitution of stock in first-aid room, pharmacy, or medical set on-board of Brazilian or foreign flag vessels under charter	RISK III	Tacit approval does not apply	60 days
Health Inspection of drugs, medical products and in vitro diagnostic products, for supply and substitution of foreign-flag vehicles, from a foreign company's fleet, that operate international collective transport of passengers	RISK III	Tacit approval does not apply	60 days
Health inspection of drugs, medical products and in vitro diagnostic products, intended for supply and substitution of first-aid room, pharmacy, or medical set on-board of vehicles that operate international collective transport of passengers	RISK III	Tacit approval does not apply	60 days
Health Inspection of drugs for hospital units or health care establishments that provide therapeutic or diagnostic services	RISK III	Tacit approval does not apply	60 days
Health Inspection of medical products for hospital units or health care establishments that provide therapeutic or diagnostic services	RISK III	Tacit approval does not apply	60 days
Health Inspection of in vitro diagnostic products for hospital units or health care establishments that provide therapeutic or diagnostic services	RISK III	Tacit approval does not apply	60 days
Inspection for consent to return of goods after repair, servicing or restoration, submitted for temporary export	RISK III	Tacit approval does not apply	60 days
Health Inspection for consent to RETURN of goods under health surveillance	RISK III	Tacit approval does not apply	60 days
Inspection for Release of the Custody and Liability Agreements of goods with pending health matters	RISK III	Tacit approval does not apply	120 days
Health Inspection for Release of goods with pending health matters	RISK III	Tacit approval does not apply	60 days
Collection and Transport of Samples for laboratory analysis of imported products subject to control analysis	RISK III	Tacit approval does not apply	60 days

Health Inspection of Substitute Import License related to import processes of products and raw materials subject to health surveillance	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection for the Ministry of Health or entities linked to the SUS (Unified Health System) of goods under health surveillance intended for the public health program	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of finished product, not regularized at ANVISA, belonging to the class of health products or in vitro diagnostic products, personal hygiene products, perfumes and cosmetics, intended for exhibition at fairs or public events	**RISK III**	**Tacit approval does not apply**	**60 days**
Inspection for consent to import, by a legal entity, of medical products used for repair or servicing purposes	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of other goods and raw materials that are part of them, part of procedure 5.6, imported by a legal entity for industrial or commercial purposes	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of chemical or environmental reference standard, by legal entity	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of raw material, intended for Quality Control of drugs, subject to registration at ANVISA	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of goods for purposes not subject to Anvisa's consent, but whose description appears in the NCM/SH listing provided for in the health legislation	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection in an international donation of samples under health surveillance linked to the monitoring, assessment, and development of Scientific Research	**RISK III**	**Tacit approval does not apply**	**60 days**
Inspection for consent to a substitute Import License whose previous LI (Import License) is exempt from the payment of a Health Surveillance Inspection Fee	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of finished product, belonging to the class of food, cosmetics, hygiene products, perfumes, household sanitizing products, health products or in vitro diagnostic products intended for demonstration at fairs or public events	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of finished product belonging to the class of food, cosmetics, hygiene products, perfumes, household sanitizing products, health products or in vitro diagnostic products intended for demonstration at fairs or public events	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of goods under health surveillance intended for Scientific and/or Technological Research, by an individual or legal entity, accredited by the CNPq (National Council for Scientific and Technological Development)	**RISK III**	**Tacit approval does not apply**	**48 hours**
Health Inspection of biological products or raw materials that compose them, part of procedure 2, imported by a legal entity for industrial or commercial purposes	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of biological products or raw materials that compose them, of products belonging to procedure 2, by a health care unit for the provision of therapeutic and diagnostic services	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of biological products or raw materials that compose them, of products belonging to procedure 2B, by a health care unit for the provision of therapeutic and diagnostic services	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of biological products or raw materials that compose them, of products belonging to procedure 2C, by a health care unit for the provision of therapeutic and diagnostic services	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of biological products or raw materials that compose them, part of procedure 2B, imported by a legal entity for industrial or commercial purposes	**RISK III**	**Tacit approval does not apply**	**60 days**

Health Inspection of up to 10 items of biological products or raw materials that compose them, part of procedure 2C, imported by a legal entity for industrial or commercial purposes	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of biological products or raw materials that compose them, of products belonging to procedure 2A, by a health care unit for the provision of therapeutic and diagnostic services	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of goods and products belonging to procedure 7, in situations of international, emergency and temporary epidemiological context	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of samples of an environmental, chemical or biological nature, intended for legal entities aimed at performing a proficiency test in private or official laboratories	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of samples of products and raw materials subject to Health Surveillance, by a legal entity authorized by the research institution of Scientific Research	**RISK III**	**Tacit approval does not apply**	**48 hours**
Health Inspection of goods under Health Surveillance, intended for SCIENTIFIC RESEARCH, conducted directly by a researcher or research institution	**RISK III**	**Tacit approval does not apply**	**48 hours**
Health Inspection of samples subject to the health surveillance regime intended for doping control tests	**RISK III**	**Tacit approval does not apply**	**60 days**
Health surveillance inspection at the entry of goods and products from abroad, intended for use in large events in the country	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of sample collection kits subject to the Health surveillance regime intended for doping control tests	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of up to 10 items whose starting material is tissues/fluids from ruminant animals, part of procedure 6, by a legal entity for industrial or commercial purposes, category IV	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of a reference standard of a chemical or environmental nature containing a substance subject to special control, by a legal entity	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection of up to 20 samples of drugs under Clinical Research containing a substance subject to special control	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection for the Ministry of Health or entities linked to the SUS, for the import of substances subject to special control provided for in Ordinance 344/98 - SVS/MS - Procedure 3, intended for a public health program	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection for the Ministry of Health or entities linked to the SUS, for the import of biological products - Procedure 2C, intended for a public health program	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection for consent to Import of reference standard intended for doping control tests	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection for consent to import of substances subject to special control provided for in Ordinance 344/98 - SVS/MS intended for doping control tests	**RISK III**	**Tacit approval does not apply**	**60 days**
Health Inspection for consent to import of health products, part of procedure 4, imported by a legal entity under the Special Deposit regime	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import of samples and standards of products subject to special control provided for in SVS/MS Ordinance No. 344, 05/12/1998 - Procedure 3 (except list C3), performed directly by a drug enforcement agency.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import of samples and standards of products subject to special control provided for in SVS/MS Ordinance No. 344, 05/12/1998 - Procedure 1 and 1A, performed directly by a drug enforcement agency.	**RISK III**	**Tacit approval does not apply**	**60 days**

Consent to import of samples and standards of products subject to special control provided for in SVS/MS Ordinance No. 344, 05/12/1998 - Procedure 1 and 1A, performed directly by a researcher or a Scientific Institution (ICT).	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import of samples and standards of products subject to special control provided for in SVS/MS Ordinance No. 344, 05/12/1998 - Procedure 1 and 1A, performed by a legal entity authorized by a researcher or a Scientific Institution (ICT).	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import of samples and standards of products subject to special control provided for in SVS/MS Ordinance No. 344, 05/12/1998 - Procedure 3 (except list C3), performed directly by a researcher or a Scientific Institution (ICT).	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import of samples and standards of products subject to special control provided for in SVS/MS Ordinance No. 344, 05/12/1998 - Procedure 3 (except list C3), performed by a legal entity authorized by a researcher or a Scientific Institution (ICT).	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import of products intended for Research involving human beings, performed directly by a Scientific, Technological and Innovation Institution (ICT).	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import of human biological samples intended for Scientific Research, performed directly by a Scientific, Technological and Innovation Institution (ICT).	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import of drugs intended for expanded access, compassionate use, post-study supply of drugs, and clinical trial programs.	**RISK III**	**Tacit approval does not apply**	**5 days**
Health Inspection for consent to import of goods or products not regularized at ANVISA by institutions that are part of the SUS, bound by the obligation of compliance with lawsuit	**RISK III**	**Tacit approval does not apply**	**immediate**
Health Inspection for consent to import of drugs and substances subject to special control, part of procedure 1 and 1A, not regularized at ANVISA by institutions that are part of the SUS, bound by the obligation of compliance with lawsuit	**RISK III**	**Tacit approval does not apply**	**immediate**

EXPRESS SHIPPING	RISK CLASSIFICATION	PREDICTABILITY	DEADLINE
Consent to export, through EXPRESS SHIPPING, of goods and products under health surveillance linked to scientific research, performed by a researcher or a Scientific, Technological and Innovation Institution (ICT).	**RISK II**	**Tacit approval does not apply**	**60 days**
Consent to export, through EXPRESS SHIPPING, of biological samples linked to scientific research, performed by a researcher.	**RISK II**	**Tacit approval does not apply**	**60 days**
Consent to export, through EXPRESS SHIPPING, of biological samples linked to scientific research, performed by a Scientific, Technological and Innovation Institution (ICT).	**RISK II**	**Tacit approval does not apply**	**60 days**
Consent to export, through EXPRESS SHIPPING, of samples of human biological material for laboratory diagnostic purposes, by an individual, for personal use.	**RISK II**	**Tacit approval does not apply**	**60 days**
Consent to export, through EXPRESS SHIPPING, of samples of human biological material for laboratory diagnostic purposes, by a legal entity.	**RISK II**	**Tacit approval does not apply**	**60 days**
Consent to export, through EXPRESS SHIPPING, of samples of human biological material resulting from clinical research, by a legal entity.	**RISK II**	**Tacit approval does not apply**	**60 days**

Consent to import, through EXPRESS SHIPPING, of goods and products subject to special control provided for in SVS/MS Ordinance No. 344, of May 12, 1998 (except Lists C1, C2 and C5), linked to scientific research, performed by third parties, an intermediary legal entity authorized by a researcher, a Scientific, Technological and Innovation Institution (ICT), or drug enforcement agencies.	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import, through EXPRESS SHIPPING, of biological samples linked to scientific research, performed by third parties, an intermediary legal entity authorized by a researcher, or a Scientific, Technological and Innovation Institution (ICT).	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import, through EXPRESS SHIPPING, of samples of advanced therapy investigational product of human biological nature to be used in a clinical trial.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import, through EXPRESS SHIPPING, of goods and products related to clinical trials with advanced therapy investigational products.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to export, through EXPRESS SHIPMENT, of goods and products subject to special control provided for in SVS/MS Ordinance No. 344, of May 12, 1998 (except Lists C1, C2 and C5), linked to scientific research, performed by a researcher or a Scientific, Technological and Innovation Institution (ICT).	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to export, through EXPRESS SHIPPING, of samples of advanced therapy investigational product of human biological nature to be used in a clinical trial.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import, through EXPRESS SHIPPING, by an individual, of products or raw materials subject to health surveillance, for individual or personal use.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import, through EXPRESS SHIPPING, of reference standard items or reference material of a non-human biological, environmental, chemical and physical nature for laboratory tests.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import, through EXPRESS SHIPPING, of samples of sanitizing products, food, and cosmetics not regularized at Anvisa for market research, laboratory analysis, quality control tests, packaging or labeling assessment, and equipment tests for product registration.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import, through EXPRESS SHIPPING, of goods and products under health surveillance linked to scientific research, performed directly by a researcher or a Scientific, Technological and Innovation Institution (ICT) accredited by the CNPQ.	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import, through EXPRESS SHIPPING, of goods and products under health surveillance linked to scientific research, performed by third parties, an intermediary legal entity authorized by a researcher, or a Scientific, Technological and Innovation Institution (ICT).	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import, through EXPRESS SHIPPING, of samples of human biological material for laboratory diagnostic purposes.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import, through EXPRESS SHIPPING, of samples of cells and tissues for therapeutic purposes.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import, through EXPRESS SHIPPING, of collection kit of biological material intended for clinical research.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import, through EXPRESS SHIPPING, of biological samples intended for doping control tests.	**RISK III**	**Tacit approval does not apply**	**60 days**

Consent to import, through EXPRESS SHIPPING, of samples of sanitizing products, food, and cosmetics not regularized at Anvisa for market research, laboratory analysis, quality control tests, packaging or labeling assessment, and equipment tests for product registration.	**RISK III**	**Tacit approval does not apply**	**60 days**
Consent to import, through EXPRESS SHIPPING, of goods and products subject to special control provided for in SVS/MS Ordinance No. 344, of May 12, 1998 (except Lists C1, C2 and C5), linked to scientific research, performed directly by a researcher, a Scientific, Technological and Innovation Institution (ICT), or drug enforcement agencies.	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import, through EXPRESS SHIPPING, of biological samples linked to scientific research, performed directly by a researcher or a Scientific, Technological and Innovation Institution (ICT).	**RISK III**	**Tacit approval does not apply**	**48 hours**
Consent to import, through EXPRESS SHIPPING, of drugs intended for expanded access, compassionate use, post-study supply of drugs, and clinical trial programs.	**RISK III**	**Tacit approval does not apply**	**5 days**

PUBLIC ACT OF RELEASE - OPERATING PERMIT	RISK CLASSIFICATION	PREDICTABILITY	DEADLINE
AE - amendment - expansion of activity	**RISK III**	**Tacit approval does not apply**	**60 days**
AE - amendment - expansion of class	**RISK III**	**Tacit approval does not apply**	**60 days**
AE - amendment - address	**RISK III**	**Tacit approval does not apply**	**60 days**
AE - amendment - compounding pharmacy - expansion of activities	**DELETED TEXT**		
AE - granting - pharmaceutical industry	**DELETED TEXT**		
AE - granting - pharmaceutical ingredients -	**DELETED TEXT**		
AE - granting - laboratories or research institutions (except industry and compounding pharmacy)	**RISK III**	**Tacit approval does not apply**	**60 days**
AE - granting - drugs - packaging company of product subject to special control	**DELETED TEXT**		
AFE - amendment - cosmetics, perfumes and hygiene products - expansion or reduction of activities	**DELETED TEXT**		
AFE - amendment - pharmacies and drugstores -	**DELETED TEXT**		
AFE - amendment - medical gases -	**DELETED TEXT**		
AFE - amendment - drugs and/or pharmaceutical ingredients -	**DELETED TEXT**		
AFE - amendment - health products - expansion or reduction of activities	**RISK III**	**Tacit approval does not apply**	**60 days**
AFE - amendment - health products - address	**RISK III**	**Tacit approval does not apply**	**60 days**
AFE - amendment - health products - merger, consolidation or spin-off of companies	**RISK II**	**Tacit approval does not apply**	**60 days**
AFE - amendment - health products - trade name	**RISK II**	**Tacit approval does not apply**	**60 days**
AFE - amendment - household sanitizing products - expansion or reduction of activities	**DELETED TEXT**	**Tacit approval does not apply**	**60 days**
AFE - granting - pharmacies and drugstores	**RISK III**	**Tacit approval pursuant to Resolution - RDC No. 275, of April 9, 2019**	**30 days**
AFE - granting - live pharmacy	**RISK III**	**Tacit approval does not apply**	**30 days**
AFE - granting - pharmaceutical ingredients - fractionator - merger, consolidation or spin-off of companies	**DELETED TEXT**	**Tacit approval does not apply**	**60 days**
AFE - granting - health products - manufacturer	**RISK III**	**Tacit approval does not apply**	**60 days**

AFE - granting - health products - storage company	**RISK III**	**Tacit approval does not apply**	**60 days**
AFE - granting - health products - storage company - merger, consolidation or spin-off of companies	**RISK II**	**Tacit approval does not apply**	**60 days**
AFE - granting - health products - distributor	**RISK III**	**Tacit approval does not apply**	**60 days**
AFE - granting - health products - distributor - merger, consolidation or spin-off of companies	**RISK II**	**Tacit approval does not apply**	**60 days**
AFE - granting - health products - packaging	**RISK III**	**Tacit approval does not apply**	**60 days**
AFE - granting - health products - exporter	**RISK II**	**Tacit approval does not apply**	**60 days**
AFE - granting - health products - exporter - merger, consolidation or spin-off of companies	**RISK II**	**Tacit approval does not apply**	**60 days**
AFE - granting - healthcare products - manufacturer - merger, consolidation or spin-off of companies	**RISK II**	**Tacit approval does not apply**	**60 days**
AFE - granting - health products - importer	**RISK III**	**Tacit approval does not apply**	**60 days**

AFE - granting - health products - importer - merger, consolidation or spin-off of companies	RISK II	Tacit approval does not apply	60 days
AFE - granting - health products - carrier	RISK II	Tacit approval does not apply	60 days
AFE - granting - health products - carrier - merger, consolidation or spin-off of companies	RISK II	Tacit approval does not apply	60 days
AFE - granting - health products - retailer	RISK II	Tacit approval does not apply	60 days
AFE - granting - health products - retailer - merger, consolidation or spin-off of companies	RISK II	Tacit approval does not apply	60 days
AFE - granting - sanitizing products - industry	DELETED TEXT		
AFE/AE - amendment - address, by public act	RISK II	Tacit approval does not apply	60 days
AFE/AE - amendment - drugs and pharmaceutical ingredients - merger, consolidation or spin-off of companies	RISK II	Tacit approval does not apply	60 days
AFE/AE - amendment - legal representative (automatic)	RISK II	Tacit approval does not apply	60 days
AFE/AE - amendment - head technician (automatic)	RISK II	Tacit approval does not apply	60 days
AFE/AE - amendment of the AFE/AE by modification in the extension of the CNPJ (Corporate Taxpayer Registration) of the headquarters, exclusively by virtue of executive declaratory act No. 34/2007 of the Federal Revenue Service of Brazil	RISK II	Tacit approval does not apply	60 days
AFE/AE - rectification of publication - Anvisa	RISK II	Tacit approval does not apply	60 days
AFE/AE - rectification of publication - pharmacies and drugstores	DELETED TEXT		
AFE/AE - rectification of publication upon request of the company	RISK II	Tacit approval does not apply	60 days

FOOD	DELETED TEXT		
COSMETIC	DELETED TEXT		
PHARMACEUTICAL INGREDIENTS	DELETED TEXT		
DRUGS	DELETED TEXT		
HEALTH PRODUCTS - (GOOD STORAGE AND/OR DISTRIBUTION PRACTICES CERTIFICATION) - Establishments in the Country	RISK III	Tacit approval does not apply	365 days
HEALTH PRODUCTS - Amendment of Trade Name in Certification - industries in other countries	RISK III	Tacit approval does not apply	60 days
HEALTH PRODUCTS - Update of International GMP Certificate as a result of corporate or commercial operations or amendment of trade name	RISK III	Tacit approval does not apply	60 days
HEALTH PRODUCTS - Update of National GMP and GSDP Certificate as a result of corporate or commercial operations or amendment of trade name	RISK III	Tacit approval does not apply	60 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of Medical Products of MERCOSUR INDUSTRY	RISK III	Tacit approval does not apply	365 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of Medical Products of MERCOSUR INDUSTRY - MDSAP	RISK III	Tacit approval does not apply	180 days

HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of Medical Products of INTERNATIONAL INDUSTRY, Except MERCOSUR	RISK III	Tacit approval does not apply	365 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of Medical Products of INTERNATIONAL INDUSTRY, Except MERCOSUR - MDSAP	RISK III	Tacit approval does not apply	180 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of Medical Products of NATIONAL INDUSTRY	RISK III	Tacit approval does not apply	365 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of Medical Products of NATIONAL INDUSTRY - MDSAP	RISK III	Tacit approval does not apply	180 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of MERCOSUR INDUSTRY	RISK III	Tacit approval does not apply	365 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of MERCOSUR INDUSTRY - MDSAP	RISK III	Tacit approval does not apply	180 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of INTERNATIONAL INDUSTRY, Except MERCOSUR	RISK III	Tacit approval does not apply	365 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of INTERNATIONAL INDUSTRY, Except MERCOSUR - MDSAP	RISK III	Tacit approval does not apply	180 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of NATIONAL INDUSTRY	RISK III	Tacit approval does not apply	365 days
HEALTH PRODUCTS - Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of NATIONAL INDUSTRY - MDSAP	RISK III	Tacit approval does not apply	180 days
HEALTH PRODUCTS - Inclusion of risk class in Certification	RISK III	Tacit approval does not apply	365 days
HEALTH PRODUCTS - Modification or addition in certification by inclusion of a new type of product line (equipment, materials and "in vitro" diagnostic product)	RISK III	Tacit approval does not apply	365 days
HEALTH PRODUCTS - Renewal of Good STORAGE AND/OR DISTRIBUTION PRACTICES Certification	RISK III	Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021	365 days
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of Medical Products of MERCOSUR INDUSTRY	RISK III	Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021	365 days
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of Medical Products of MERCOSUR INDUSTRY - MDSAP	RISK III	Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021	180 days
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of Medical Products of INTERNATIONAL INDUSTRY, Except MERCOSUR	RISK III	Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021	365 days
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of Medical Products of INTERNATIONAL INDUSTRY, Except MERCOSUR - MDSAP	RISK III	Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021	180 days
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of Medical Products of NATIONAL INDUSTRY	RISK III	Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021	365 days
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of Medical Products of NATIONAL INDUSTRY - MDSAP	RISK III	Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021	180 days

HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of MERCOSUR INDUSTRY	**RISK III**	**Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021**	**365 days**
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of - MDSAP	**RISK III**	**Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021**	**180 days**
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of INTERNATIONAL INDUSTRY, Except MERCOSUR	**RISK III**	**Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021**	**365 days**
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of INTERNATIONAL INDUSTRY, Except MERCOSUR - MDSAP	**RISK III**	**Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021**	**180 days**
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of NATIONAL INDUSTRY	**RISK III**	**Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021**	**365 days**
HEALTH PRODUCTS - Renewal of Good MANUFACTURING Practices Certification of In Vitro Diagnostic Products of NATIONAL INDUSTRY - MDSAP	**RISK III**	**Tacit approval pursuant to Resolution - RDC No. 497, of May 20, 2021**	**180 days**
HEALTH PRODUCTS - Rectification of Publication - COMPANY	**RISK III**	**Tacit approval does not apply**	**60 days**
SANITIZING PRODUCTS -	**DELETED TEXT**		

This content does not replace the text published in the certified version.

The deleted texts are in the original version, available only in Portuguese.