COLLEGIATE BOARD RESOLUTION – RDC No. 939 OF 14 NOVEMBER 2024

Establishes the criteria for applying for Operating Authorizations and Special Authorizations for companies storing goods and products subject to health control and inspection in Customs Warehouses, Operating Authorizations for importers on behalf of third parties or by order of goods and products subject to health control and inspection, as well as exemption from Operating Authorizations for other companies providing services at Ports, Airports, and Borders.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, items III and IV, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 53, item VI, Paragraphs 1 and 3 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 13 November 2021, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Object

Article 1. This Resolution establishes:

I – the criteria for granting, modifying, and canceling Operating Authorizations (AFE, in Portuguese) and Special Authorizations (AE, in Portuguese) for companies that store goods and products subject to health control and inspection in customs warehouses, as well as AFEs for importers on behalf of third parties or by order of goods and products subject to health control and inspection; and

II – the exemption from AFEs for companies that provide services of health interest in land vehicles operating international public passenger transport, vessels, aircraft, waterway terminals, organized ports, airports, border posts, and customs facilities.

Section II

Scope

Article 2. This Resolution applies to companies that:

I – store goods and products subject to health control and inspection in customs warehouses; and

II – import goods and products subject to health control and inspection on behalf of a third party or by order.

Paragraph 1. The provisions of Item I of the caption of this article include express and postal shipping companies.

Paragraph 2. The provisions of Item I of the caption of this article do not apply to duty-free shops, special warehouses, and warehouses that exclusively store bulk cargo of food or vegetable oils.

Section III

Definitions

Article 3. For the purposes of this Resolution, the following definitions apply:

I – customs clearance: authorization by the Special Secretariat of the Brazilian Federal Revenue Service (RFB, in Portuguese) to carry out, in the locations or enclosures specified under customs control, the movement, storage, and customs clearance of goods and products originating from abroad or destined for abroad, including those under a special customs regime;

II – customs warehouse: area declared by the competent customs authority, in the primary or secondary zone, where the storage and customs clearance of goods and products subject to health control and inspection (originating from abroad or destined for abroad) takes place under customs control;

III – storage: safekeeping, movement, handling, and preservation of goods and products, whether unloaded or not;

IV – Operating Authorization (AFE, in Portuguese): an act under the jurisdiction of the Brazilian Health Regulatory Agency, authorizing the operation of companies or establishments, institutions, and agencies, granted upon compliance with the technical and administrative requirements set forth in this Resolution;

V – Special Authorization (AE, in Portuguese): an act under the jurisdiction of the Brazilian Health Regulatory Agency, authorizing the exercise of activities involving medicinal products and substances subject to special control, upon proof of specific technical and administrative requirements set forth in this Resolution;

VI – goods and products subject to health control and inspection: materials, raw materials, inputs, parts, finished products, bulk products, semi-finished products, and *in natura* products, and other items subject to health surveillance as set forth in Law No. 9,782 of 1999, including, among others, medicinal products, food, cosmetics, sanitizing products, medical devices, cells, tissues, and organs;

VII – bulk cargo: liquid or dry cargo shipped and transported without packaging, without identification markings, and without unit counts;

VIII – technical-operational conditions: minimum conditions for commencing activities, demonstrating adequate technical and operational capacity for storing goods and products subject to health control and inspection;

IX – import on behalf of a third party: where the importing legal entity is contracted to arrange, on its behalf, customs clearance for the import of goods or products subject to health control and inspection of foreign origin acquired abroad by another legal entity;

X – import by order: where the importing legal entity is contracted to arrange, on its behalf and using its own resources, customs clearance for the import of goods or products subject to health control and inspection of foreign origin acquired abroad for resale to a predetermined ordering party;

XI – administrative headquarters: headquarters that does not store products subject to health surveillance;

XII – legal representative: an individual designated in the bylaws, articles of association, or articles of incorporation to represent the company, actively and passively, in judicial and extrajudicial proceedings; and

XIII – technical manager: a professional legally qualified by the respective professional council for the activity the company performs with products covered by this Regulation.

CHAPTER II

OPERATION AUTHORIZATION AND SPECIAL AUTHORIZATION FOR COMPANIES THAT STORE GOODS AND PRODUCTS SUBJECT TO HEALTH CONTROL AND INSPECTION

Section I

General provisions

Article 4. Companies that store goods and products subject to health control and inspection in customs warehouses are subject to the AFE.

Article 5. The AFE referred to in this Chapter will be granted in the Brazilian Registry of Legal Entities (CNPJ, in Portuguese) of the company's headquarters and will be valid throughout Brazil.

Paragraph 1. The branch of the company referred to in the caption of this article that, as a customs warehouse, stores goods and products subject to health control and inspection, must file a branch registration request with Anvisa prior to its commencement of operations, accompanied by the documentation defined in Annex I of this Resolution.

Paragraph 2. The branch mentioned in Paragraph 2 of Article 8 is exempt from the provisions of the previous paragraph.

Article 6. In addition to being subject to the AFE, establishments that store in customs warehouses substances included in the lists attached to SVS/MS Ordinance No. 344 of 12 May 1998, and its updates, and medicinal products containing them, are also subject to the AE.

Article 7. The AE must be requested for each establishment that stores substances subject to special control and medicinal products containing them.

Sole paragraph. For the storage of medicinal products or pharmaceutical inputs for human use containing substances subject to special control, in addition to the AE, the AFE for storage of

medicinal products or pharmaceutical inputs is required, in the case of a head office, and branch registration, in the case of a subsidiary establishment.

Article 8. Companies must request the granting, alteration, or cancellation of the AFE, branch registration, and AE for the activity of storing goods and products subject to health control and inspection, through an electronic request on Anvisa website.

Paragraph 1. The granting of the AFE and AE, branch registration, and change of address will depend on an inspection of the customs warehouse by the competent health authority, with a satisfactory conclusion regarding the Technical Operational Conditions for the storage of goods and products subject to health control and inspection, and a technical opinion favorable to granting the request.

Paragraph 2. The granting of an AFE for an administrative head office is subject to proof of the Technical Operational Conditions for a branch of the same company to perform the requested activity.

Paragraph 3. Changing the address of the administrative headquarters does not require a health inspection.

Paragraph 4. The AE protocol may be submitted concurrently with the AFE application or registration of a pharmaceutical branch, or after the granting of the AE is published.

Paragraph 5. If the company's AFE application is denied, the requests for branch registration and AE granting will also be denied.

Article 9. The documentation to be submitted when requesting granting, alteration, or cancellation of the AFE or AE is listed in Annex I of this Resolution.

Article 10. The documents listed in Annex I of this Resolution that require the signature of the legal representative or technical manager must be submitted to the health authority with a valid and verifiable digital signature, with a certificate issued by certifying authorities recognized by the Brazilian Public Key Infrastructure (ICP/Brasil).

Article 11. The professional training of the technical manager of the companies covered by this Chapter must meet the requirements for this purpose, as set forth in the relevant legislation related to the class of product to be stored.

Sole paragraph. The professional's technical responsibility certificate, issued by a regulatory entity for the professional practice, must demonstrate their connection with the establishment applying for the AFE, branch registration or AE, and specify the storage activity of the product class for which the company requests a concession or alteration.

Article 12. The AFE must be filed for each of the following product classes and their raw materials:

I – medicinal products;

II – food;

III – cosmetics and hygiene products;

IV – sanitizing products; and

V – medical devices.

Article 13. Prior petitioning with Anvisa is mandatory for the following alterations:

I – change of corporate name;

II – change of address;

III – change of technical manager;

IV – change of legal representative; and

V – branch registration.

Paragraph 1. The obligations referred to in items II, III, and IV of the caption of this article apply to the head office and branch units registered in the Operating Authorizations referred to in articles 4 and 6 of this Resolution.

Paragraph 2. The mandatory request for a change of corporate name applies only to the company's head office.

Paragraph 3. Expansion or reduction of the storage area of the premises must be communicated to Anvisa through an amendment protocol.

Paragraph 4. The change referred to in item II of the caption of this article will only be granted after proof of customs clearance at the new address.

Paragraph 5. The change referred to in item V of the caption of this article will only be granted after the AFE has been granted to the company's head office.

Article 14. Upon termination of the company's activities as described in this Resolution, a petition for cancellation of the AFE or AE must be filed with Anvisa.

Article 15. In the event of a change to the company's CNPJ (Brazilian Registry of Legal Entities), a new grant must be filed, as well as the cancellation of the AFE or AE of the old CNPJ.

Section II

Technical and operational conditions

Article 16. Customs warehouses that store goods and products subject to health surveillance must meet the following technical requirements for granting AFE, AE, or branch registration, which will be assessed during a health inspection:

a) existence of necessary facilities, equipment, and instruments in conditions suitable for their intended purpose, including qualifications and calibrations;

b) existence of qualified personnel duly trained to perform the establishment's activities;

c) hygiene, storage, and operating conditions appropriate to the activities to be performed and the product's needs, in order to reduce the risk of contamination or alteration of its characteristics;

d) standard operating procedures for receiving, identifying, inventory control, and storage of goods and products;

e) a separate, identified area with access control for the storage of products or substances subject to special control in the event of an AE request;

f) a dedicated area for the storage of goods and products subject to health control and inspection that meets the product storage requirements;

g) area or location for storage of prohibited goods and products;

h) a separate and secure area or location for hazardous, explosive, flammable, toxic, or other cargo that poses a potential risk to life or health, or that requires special storage care;

i) an area or location suitable for physical or remote inspection of cargo, including in refrigerated areas (when applicable);

j) adequate receiving, shipping, and storage areas protected from inclement weather, such as rain, wind, extreme heat, cold, solar radiation, dust, and harmful synanthropic animals;

k) an inventory control system that allows for the issuance of inventories;

l) an established quality manual or equivalent document;

m) solid waste management; and

n) procedures for controlling vectors and harmful synanthropic animals.

CHAPTER III

AUTHORIZATION TO OPERATE FOR COMPANIES THAT IMPORT ON BEHALF OF A THIRD PARTY OR BY ORDER OF GOODS AND PRODUCTS SUBJECT TO HEALTH CONTROL AND INSPECTION

Article 17. Companies that import, on behalf of a third party or by order of goods and products subject to health control and inspection, are subject to the AFE.

Article 18. The AFE referred to in this Chapter will be granted to the CNPJ (Brazilian Registry of Legal Entities) of the company's headquarters and is valid throughout the Brazilian territory.

Sole paragraph. The branch of the company referred to in the caption of this article, which imports goods and products subject to health control and inspection, must file a branch registration application with Anvisa prior to its start of operations, accompanied by the documentation defined in Annex II of this Resolution.

Article 19. Companies must request the granting, alteration, or cancellation of the AFE and registration of a branch for importing goods and products subject to health control and inspection on behalf of a third party or by order through an electronic request on Anvisa website.

Article 20. The documentation to be submitted when requesting the granting, alteration, or cancellation of the AFE is listed in Annex II of this Resolution.

Article 21. The documents listed in Annex II of this Resolution that require the signature of the legal representative must be submitted to the health authority with a valid and verifiable digital signature, with a certificate issued by certifying authorities recognized by the Brazilian Public Key Infrastructure (ICP/Brasil).

Article 22. The AFE for importing goods and products subject to health control and inspection on behalf of a third party or by order must be filed for each of the following product classes and their raw materials:

I – medicinal products;

II – cosmetics and hygiene products;

III – sanitizing products; and

IV – medical devices.

Article 23. Prior petitioning of the following alterations to Anvisa is mandatory:

I – corporate name;

II – address;

III – legal representative; and

IV – branch registration.

Article 24. Upon termination of activities of the companies described in this Resolution, a petition for cancellation of the AFE must be filed with Anvisa.

Article 25. In the event of a change to the company's CNPJ (Brazilian Registry of Legal Entities), a new granting protocol will be required, as well as cancellation of the AFE for the old CNPJ.

CHAPTER IV

FINAL PROVISIONS

Article 26. Companies that provide services of public health interest in land vehicles operating international public passenger transportation, vessels, aircraft, waterway terminals, organized ports, airports, border posts, and customs facilities are exempt from AFE, namely:

I – business administration or representation, on behalf of the legal representative or person directly responsible for the vessel, taking the necessary measures for its clearance at organized ports and waterway terminals located in Brazilian territory;

II – pest control or deratization of land vehicles in transit through border posts, vessels, aircraft, waterway terminals, organized ports, airports, border posts, and customs facilities;

III – supply of drinking water for human consumption on board land vehicles operating international public passenger transportation, aircraft, and vessels;

IV – cleaning, disinfection, or decontamination of surfaces of land vehicles in transit through border posts, aircraft, vessels, waterway terminals, organized ports, airports, border posts, and customs facilities;

V – cleaning and collection of wastewater and waste treatment at waterway terminals, organized ports, airports, border posts, and customs facilities;

VI – drainage, collection, and treatment of sewage effluents from land vehicles in transit through border posts, aircraft, vessels, airports, waterway terminals, organized ports, and border posts;

VII – segregation, collection, packaging, storage, transportation, treatment, and final disposal of solid waste from land vehicles in transit through border posts, aircraft, vessels, waterway terminals, organized ports, airports, border posts, and customs facilities;

VIII – barbershops, hairdressers, and pedicures in waterway terminals, organized ports, airports, and border posts;

IX – beauty salons and similar establishments, including body relaxation services, located in waterway terminals, organized ports, airports, and border posts;

X – laundry services in waterway terminals, organized ports, airports, and border posts;

XI – medical care in waterway terminals, organized ports, airports, and border posts;

XII – hotels in waterway terminals, organized ports, airports, and border posts;

XIII – support points for land vehicles operating international public passenger transportation; and

XIV – express shipping companies that do not have a customs warehouse.

Paragraph 1. Companies trading in medical and hospital materials and equipment and pharmacies and drugstores located in water terminals, organized ports, airports, and border posts must comply with the provisions of RDC No. 16, of 1 April 2014, and RDC No. 275, of 9 April 2019, and others that may replace them.

Paragraph 2. The companies referred to in the caption of this article, despite being exempt from AFE, must comply with the provisions of the relevant health legislation and are subject to inspection by the health authority.

Paragraph 3. When requested by the competent health surveillance agencies, the companies referred to in the caption of this article must provide information or submit documents within the established deadlines, as well as comply with the Health Notification, so as not to impede surveillance actions and any necessary measures.

Paragraph 4. The companies referred to in Item XIV of the caption of this article, despite being exempt from AFE, must ensure adequate storage, in accordance with Good Storage Practices, of goods and products subject to health surveillance, in a location duly authorized by Anvisa to store the product class.

Article 27. Anvisa may, at any time, following due legal process, cancel the AFE and AE of companies or establishments, if facts justify such a measure.

Paragraph 1. Cancellation of a company's AFE for a product class results in the cancellation of the registrations of associated branches.

Paragraph 2. Cancellation of the AFE or the registration of a branch of medicinal products and pharmaceutical inputs results in the cancellation of the AEs.

Article 28. Failure to comply with the provisions contained in this Resolution constitutes a health violation, under Law No. 6,437 of 20 August 1977, without prejudice to other applicable civil, administrative, and criminal liabilities.

Article 29. Petitions from companies referred to in Article 26, filed with Anvisa prior to the publication of this Resolution, will be closed, and the Health Surveillance Inspection Fee will not be refunded if analyses have already begun.

Article 30. The following are revoked:

I – Collegiate Board Resolution – RDC No. 345 of 16 December 2002, published in the Federal Official Gazette No. 245 of 19 December 2002, Section 1, page 144;

II – Annexes I and II of Collegiate Board Resolution – RDC No. 346 of 16 December 2002, published in the Federal Official Gazette No. 245 of 19 December 2002, Section 1, page 147;

III – Items I to XII, except Item IX, of Article 57 of Collegiate Board Resolution – RDC No. 2 of 8 January 2003, published in the Federal Official Gazette No. 9 of 13 January 2003, Section 1, page 45;

IV – Collegiate Board Resolution – RDC No. 61 of 19 March 2004, published in the Federal Official Gazette No. 55 of 22 March 2004, Section 1, page 31;

V – Item XI of Article 4 and Article 91 of RDC No. 661 of 30 March 2022, published in the Federal Official Gazette No. 62 of 31 March 2022, Section 1, page 334; and

VI – Section I of Article 31 of RDC No. 664 of 30 March 2022, published in the Federal Official Gazette No. 62 of 31 March 2022, Section 1, page 338.

Article 31. This Resolution shall come into effect 20 (twenty) days after the date of its publication.

ANTONIO BARRA TORRES

Director-President

ANNEX I

DOCUMENTS REQUIRED IN OPERATING AUTHORIZATION AND SPECIAL AUTHORIZATION PROTOCOLS FOR COMPANIES THAT STORE GOODS AND PRODUCTS SUBJECT TO HEALTH CONTROL AND INSPECTION, BY TYPE OF PETITION.

Type of petition	Required documents marked with an "X"						
	1	2	3	4	5	6	7
Concession	X	X	X	X	X	X	
Branch Registration	X	X	X	X	X	X	
Change of Company Name	X	X					
Change of address	X	X	X	X	X		
Change of address determined by Public Act	X						X
Change of Technical Manager	X		X				
Change of Legal Representative	X	X					
Cancellation	X						

Key:

1 – Operating Authorization Petition Form for the storage of goods under health surveillance at ports, airports, border posts, and customs facilities, digitally signed by the company's legal representative listed in the articles of association and the technical manager.

2 – Articles of Association or Articles of Incorporation, registered with the Board of Trade, and any amendments, if any. This document must include the requested activity(ies) as its corporate purpose.

3 – Certificate of Good Standing, Statement of Responsibility, or Declaration of Affiliation of the Technical Manager, issued by the Regulatory Entity for the professional activity, proving their affiliation with the requesting establishment and specifying the requested activities.

4 – Descriptive report of the facilities and equipment, including cold/air-conditioned chambers that the company has for the requested activity(ies), detailing their temperature specifications, capacity, and functions/uses, digitally signed by the technical manager.

5 – Floor plan of the establishment with flow control, access restrictions, location for cargo inspection, and internal and yard storage areas, digitally signed by the technical manager.

6 – Customs Clearance Declaratory Act or Customs Clearance Qualification Declaratory Act.

7 – Copy of the Public Act that originated the requested alteration.

ANNEX II

DOCUMENTS REQUIRED IN THE OPERATING AUTHORIZATION PROTOCOLS OF COMPANIES THAT CARRY OUT IMPORT ACTIVITIES ON BEHALF OF A THIRD PARTY OR TO ORDER GOODS AND PRODUCTS SUBJECT TO HEALTH CONTROL AND INSPECTION, BY TYPE OF PETITION

Type of petition	Required documents marked with an "X"		
	1	2	3
Concession	X	X	
Branch Registration	X	X	
Change of Company Name	X	X	
Change of address	X	X	
Change of address determined by Public Act	X		X
Change of Legal Representative	X	X	
Cancellation	X		

Key:

1 – Operating Authorization Petition Form for the storage of goods under health surveillance at ports, airports, border posts, and customs facilities, digitally signed by the company's legal representative listed in the articles of association and the technical manager.

2 – Articles of Association or Articles of Incorporation, registered with the Board of Trade, and any amendments, if any. This document must include the requested activity(ies) as its corporate purpose.

3 – Copy of the Public Act that originated the requested alteration.