COALICIÓN INTERAMERICANA PARA LA CONVERGENCIA REGULATORIA SECTOR DE TECNOLOGÍA MÉDICA | COALIZÃO INTERAMERICANA PARA CONVERGÊNCIA REGULATÓRIA SETOR DE TECNOLOGIA MÉDICA | INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE MEDICAL TECHNOLOGY SECTOR

Inter-American Coalition for Regulatory Convergence – Medical Technology Sector (IACRC)

White Paper

Certificates of Free Sale (CFS) / Certificates to Foreign Government (CFGs)

Introduction

The objectives of this paper are:

Part I To provide clarifying definitions related to **Certificates of Free Sale (CFS) / Certificates to Foreign Government (CFG)** as they apply to MD/IVDs.

Part II To present the recommendations of the Inter-American Coalition for Regulatory Convergence – Medical Technology Sector regarding modernization of medical device regulatory frameworks that require CFS/CFGs.

Part III To provide a summary of the main requirements and legal backgrounds of selected Latin American countries in relation to the presentation of CFS/CFGs.

Part I

Fact Sheet & Definitions

The **Certificate of Free Sale (CFS)**, the **Free Sale Certificate (FSC), the Certificate to Foreign Government (CFG), the Certificate of Free Trade (CFT) and the Declaration of Free Sale (DFS)** (hereafter referred to as "**CFS/CFG")** are different nomenclatures for the same document. Whichever term is used, these documents are meant to constitute one or all of the following: a) a document providing a level of attestation that a product does not suffer any commercialization restriction in the market in which it was manufactured or marketed; b) a document stating that a product complies and is in compliance with the regulations and technical norms of the country of origin and, thus, is able to enter the market of the **importing** country as condition of the importing country authorities; and c) it is a document able to make possible the registration of the product in the importing country, enabling the manufacturing company to participate in bids and other events in the importing country or to establish the conditions under which the CFS may be dispensed with for future exports.

Export-Only Certificates: A Certificate of Exportability (COE) may be issued, upon request, for the export of MD/IVDs that may not be legally marketed in the origin country and that meet certain requirements for exportability.

United States: In the U.S., the CFS is also known as Certificate to Foreign Government (CFG). The CFG is for the export of MD/IVDs that can be legally marketed in the U.S. and follow the

requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Any MD/IVD that is legally marketed in the U.S. may be exported anywhere in the world without prior FDA notification or approval. U.S. establishments may request a CFG for any MD or IVD that may be legally marketed in the U.S. The U.S. does not require CFG for imported MD/IVDs that enter the U.S. market. A COE under Section 802 (COE 802) may be issued, upon request, for the export of medical devices that may not be legally marketed in the U.S. and that meet the requirements of Section 802 of the FD&C Act. Unapproved Class III devices and Class II devices that are required to meet performance standards under Section 514 of the FD&C Act can be exported under Section 802 of the FD&C Act if the establishments and the devices meet certain criteria. These include investigational devices, unapproved devices that did not obtain PMA approval (or for which a PMA has not been approved) and banned devices.

Apostille: An Apostille is a type of notarization, issued by a designated authority, that "authenticates" the origin of a public document so that it may be presented in another country as one traditional mechanism to provide an increased level of confidence that the document is authentic and not a forgery. Formally, the Hague Convention of 5 October 1961 "Abolishing the Requirement of Legalization for Foreign Public Documents" (the "Apostille Convention") provides the international legal framework governing Apostilles. Countries that are not members of the Apostille Convention cannot ask for an Apostille and must follow the traditional path for the legalization of documents.

The Apostille Convention only applies to "public documents" exemplified therein (a public document is defined as such by the origin country, which issues the document). Apostilles may only be issued by Competent Authorities formally designated by its Contracting Parties. The only effect of an Apostille is to certify the authenticity of the signature, the capacity in which the person signing the document has acted, and the identity of the seal or stamp which the document bears. The Apostille does not authenticate the content of the underlying public document. A Contracting Party must designate the authorities that are competent to issue Apostilles. Each Contracting Party is free to determine the identity and number of its Competent Authorities. Under the Convention, they perform three fundamental functions: verifying the authenticity (origin) of public documents; issuing Apostilles; and recording issued Apostilles in their register, to facilitate, at the request of a recipient, the verification of an Apostille.

Public documents are increasingly being executed in electronic format in many States with the support of laws recognizing electronic signatures as the functional equivalent of "wet" signatures. To apply paper Apostilles to such documents involves reproducing the document in paper form and, depending on the applicable law, having the paper version certified as a true copy of the "original" electronic public document. Not only is this process cumbersome, it also means that the advantages of using the "original" document are lost in terms of improved security and transmissibility.

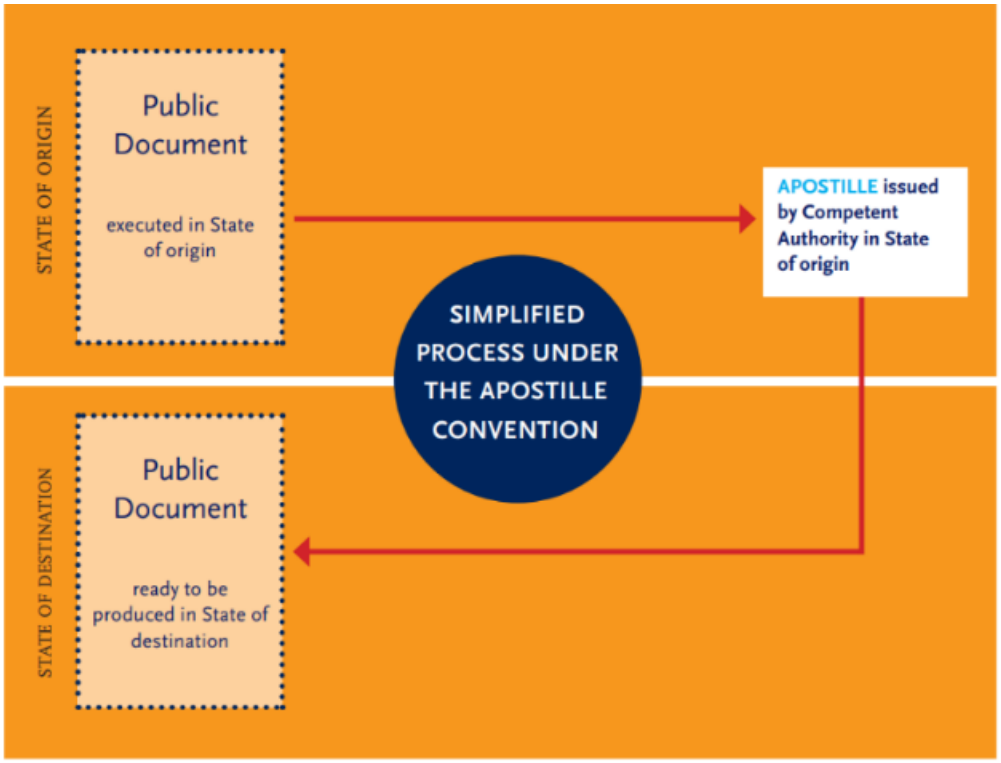
The electronic Apostille Programme (e-APP) was launched in 2006 to promote and assist in the implementation of technology under the Apostille Convention. It allows improvements to be made

to the accessibility and usability of the Convention using commonly available technologies. There are two components to the e-APP: e-Apostilles and e-Registers. An **e-Apostille** is an Apostille issued in electronic form and signed by electronic signature with a digital certificate. e-Apostilles may be issued on electronic documents or on paper documents that have been scanned into electronic form. An **e-Register** is a register maintained in a publicly accessible platform, in electronic form, which allows any interested person to verify their Apostille online. An e-Register can be operated to record the issuance of both paper Apostilles and e-Apostilles.

American Countries that have the e-Apostille and e-Register already in place: Argentina, Brazil, Bolivia, Chile, Colombia, Dominican Republic, El Salvador, Guatemala, Peru and Venezuela.

Countries in the Americas that have only the e-Register in place include Costa Rica, Ecuador, Mexico, Nicaragua, Paraguay, United States, Uruguay.

Figure 1 - Apostille Process

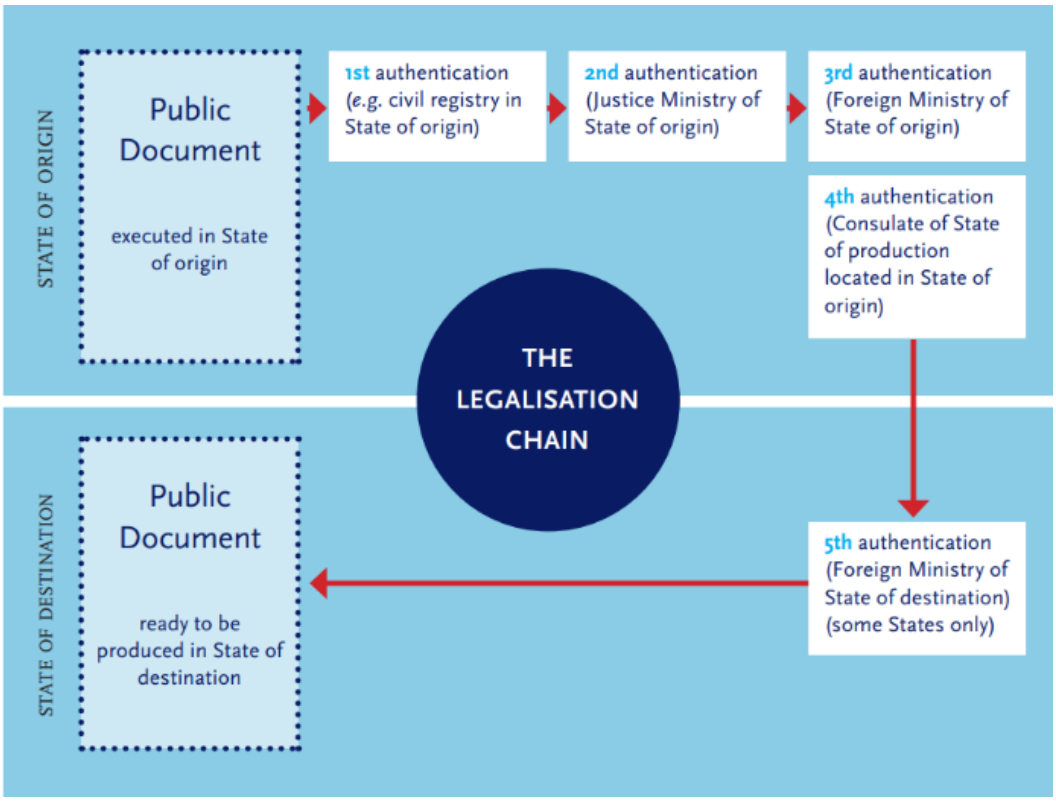


Source: Hague Apostille Handbook

Traditional Legalization Process: Legalization describes the procedures whereby the signature / seal / stamp on a public document is certified as authentic by a series of public officials along a "chain" to a point where the ultimate authentication is readily recognized by an official of the State of destination and can be given legal effect there. As a practical matter, Embassies and Consulates of the State of destination located in (or accredited to) the State of origin are ideally situated to facilitate this process. However, Embassies and Consulates do not maintain samples of the

signatures / seals / stamps of every authority or public official in the State of origin, so an intermediate authentication between the authority or public official that executed the public document in that State and the Embassy or Consulate is often required. In most cases, this involves an authentication by the Ministry of Foreign Affairs of the State of origin. However, depending on the law of the State of execution, a series of authentications may be required before the document can be presented to the Embassy or Consulate for authentication. Then, depending on the law of the State of destination, the seal / stamp of the Embassy or Consulate may be recognized directly by the official in that State, or may need to be presented to the Ministry of Foreign Affairs of that State for a final authentication.

Figure 2 – Legalization Process



Source: Hague Apostille Handbook

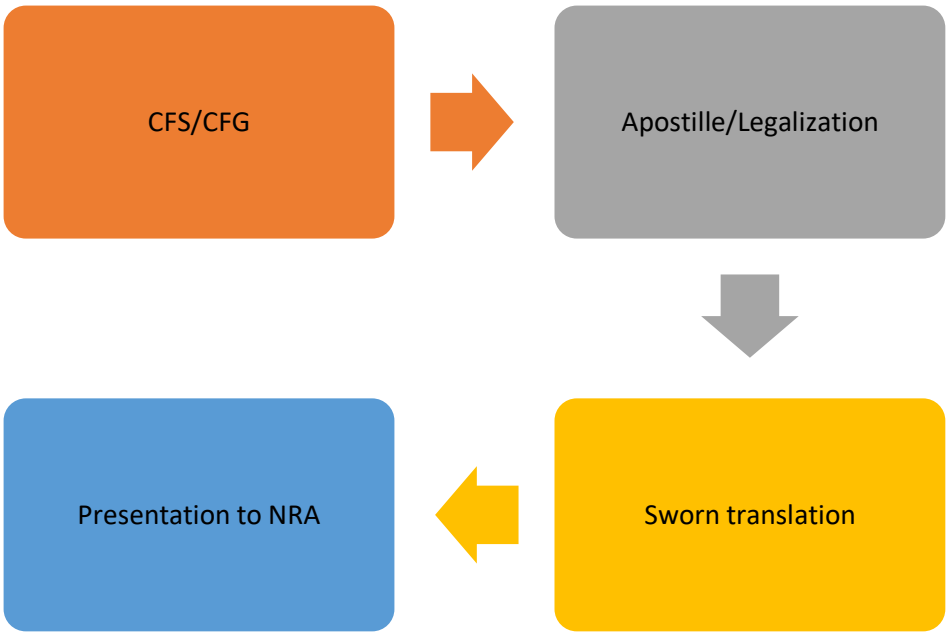
Sworn translation: The documents issued in languages different from that of an importing country may have to be translated into the national language of the country in which the document is expected to be accepted. The sworn translation is a certified translation carried out by a sworn translator (also referred to as Official Public Translator and Commercial Interpreter). It is officially recognized by institutions and public authorities and is regarded as an official document.

Before making any translation arrangements, one must check directly with the authority where the document will be submitted whether the translation must be carried out by an Official Public

Translator and Commercial Interpreter in the country or whether it can be done by a certified translator abroad.

The figure below illustrates the whole procedure of internalization of the CFS/CFG to the national regulatory authorities.

Figure 3 – Complete Process for Presentation CFS/CFG



Trade Considerations: Select trade agreements also constitute treaty-based obligations and commitments with the force of international law that limit the requirement of market authorizations in an exporting country as a condition of grating marketing authorization in an importing country.

As one example, the United States-Mexico-Canada Agreement (USMCA) – Chapter 12-E – Medical Device Sectoral Annex, article 12.E.6 Market Authorization - Item 5 states:

> "No Party shall require that a medical device receive a marketing authorization from a regulatory authority in the country of manufacture as a condition for the medical device to receive marketing authorization from that Party."

Part II

IACRC Positioning on

Certificates of Free Sale (CFS) / Certificates to Foreign Government (CFGs)

Considering that:

- Certificates of Free Sale (CFS) / Certificates to Foreign Government (CFG), initially established in the 1970's, were measures to enable and promote international regulatory and trade certainty – in particular as a type of authentication of documentation, but after years of global cooperation, modern paperless trade and regulatory tools and mechanisms are available that can be used to ensure proper regulatory and trade oversight between governments.

- Over the last decades, National Regulatory Authorities (NRAs) have evolved their assessment procedures from just a simple legal review to a scientific evidence-based assessment to ensure the quality, safety, efficacy and/or performance of medical devices including In-Vitro Diagnostics ("MD/IVDs").

- The information provided in CFS/CFGs is now available and assessable in many jurisdictions any day and time via trusted sources from government authorities or multilateral organizations such as the US FDA, EU Commission, World Health Organization (WHO) websites or digital databases.

- On 10 July 2023, the U.S. Food and Drug Administration (FDA) communicated that beginning December 2023, it will begin transitioning from paper export documents for medical devices to electronic export documents and that all certificate request reviews completed by the FDA after 2 January 2024 will be issued electronically.

- There are many countries in the Americas which currently require a CFS/CFG for regulatory, customs and procurement purposes for imported medical devices including in vitro diagnostics.

- Some countries require such certificates to go through an additional validation process requiring an Apostille and/or legalization and sworn translations.

- Apostilles may only be issued by designated government bodies. In the United States, they may be U.S State-level Departments of State, or the U.S. State Department. Some countries such as Argentina, Colombia, Costa Rica, and Uruguay additionally require that Apostilles be issued by the U.S. Department of State in Washington, DC, which is currently suffering a backlog of approximately 12-16 weeks.

- These processes may not currently accept electronic documents according to local policies or regulations and therefore, the lack of paper certificates is anticipated to potentially disrupt or prevent the registration, import and market authorization of MD/IVDs from the U.S. with a material impact on patient access to MD/IVDs in the Americas

- Transitioning regulatory, customs and procurement control documentation into electronic processes is a core aspect of medical device regulatory convergence to reduce unnecessary costs and to improve patient access. However, the transition constitutes a challenge to authorities and patients in affected countries. Therefore, a transition should be planned to avoid disruption and future regulatory, import/export and procurement policy requirements should be updated to eliminate the need for paper copies.

The Inter-American Coalition for Regulatory Convergence – Technological Medical Sector ("IACRC") observes that:

- The rationale behind the requirement for the CFS/CFG by authorities is ostensibly to secure the proper authorization, import, procurement and export of MD/IVDs.

- However, there are countries, such as Brazil and the U.S.,[1] that have secure procedures and tools which control and guarantee the regulatory authorization, import and export, distribution and sale of high-quality and safe medical products without the need or condition to issue and/or use CFS/CFG in another Party's territory.

    - For example, the information provided in a CFS/CFG is already provided by, and is redundant with, the information publicly available on the freely available, digital and online FDA Medical Devices Database.

- The Trade Facilitation Agreement (TFA) of the World Trade Organization (WTO) endeavors to eliminate measures or requirements that are trade restrictive and stimulate countries to implement reasonable alternatives that are less trade restrictive.

- The elimination of the CCFS/CFG and the implementation of alternative measures that have the same effect on the regulatory, customs and procurement control of the imported MD/IVDs should be considered by all WTO members.

- The entire procedure for the issuance of CFS/CFG, Apostille and legalization as well as sworn translations may not be adequate or suitable for electronic documents.

- Government authorities will be able to verify the authenticity of an export certificate through the FDA/CDRH Export Certification Application and Tracking System (CECATS) and the FDA unified registration and listing systems (FURLS) Export Certificate Validator (FECV)

[1] Legislation available on Part II of this document.

databases. The Apostille process is not the only way to verify the authenticity of the document.

- The critical importance of MD/IVDs to general public health, pandemic response and health emergency preparedness, demand an effort to maximize the resiliency of the medical products supply chain.
- A key lesson learned from the pandemic is that it is required to improve the agility of existing procedures removing steps or requirements that no longer add a real value to ensure proper regulatory, customs and procurements controls, considering the important advancements on global connectivity and digitalization to benefit patient's safety and access.

Given the above, the position of the **IACRC** is as follows:

1. Countries should make an effort to embed digitization and digitalization in the local regulations, including those applicable to monitor and control the authorization, procurement, import and export of medical products.
2. The Authorities of importing countries should remove the requirement for a CFS/CFG if the MD/IVD is already approved by an internationally recognized regulatory agency/body and/or is already exported to selected countries (such as the U.S., Brazil) that do not always require the CFS/CFG.
3. Countries that still require a CFS/CFG should nonetheless endeavor to accept the official electronic format of these certificates and without the requirements of an Apostille or legalization.
    - As rationale,
        a. The IACRC is unaware of any public data that demonstrates that the requirements for an Apostille issued by the U.S. Department of State or any U.S. State level Department of State of a CFG issued by the FDA provides any real measure of reducing falsified documents from being accepted.
        b. The IACRC is similarly unaware of any Regulatory Impact Assessment (RIA) that has been conducted on the benefits or necessity of requiring CFS/CFG.
        c. The IACRC is of the position that reference National Regulatory Authorities, such as the FDA and ANVISA, have well-established public faith and that documents issued by these NRAs do not require authentication by any other entity of the U.S., Brazil or other government.

d. The IACRC is of the position that even if the Apostille process provided some level of preventing the presentation of falsified documents, the approach is not risk-based and it is overly burdensome for the stated purpose with the costs not outweighing the benefits. There are other modern digital tools now available to determine the authenticity of a document with a level of security superior to paper-based approaches.

e. The lack of a RIA and together with the lack of a risk-based approach is at odds with the drive for the implementation of Good Regulatory Practices in the Americas as supported by the GRP Declaration of 2022 from the Summit of the Americas.

f. The issuance of CFG/CFSC and their subsequent legalization or Apostille process represents a critical supply chain bottleneck within the regulatory requirements of the countries that require it as it is a process whose issuance, legalization, translation can take more than six to ten weeks. This impacts the availability of the health registrations necessary for the market authorization of medical devices into countries in the Western Hemisphere.

4. In case there is a need for translation of the official electronic CFS/CFG the country should commit to accept the sworn translation of the electronic document:

    - Paper documents are an anachronism in the 21st Century. Their handling is unnecessarily cumbersome, time-consuming and costly. Their issuance and transportation are difficult during normal times, and often impeded or impossible during times of emergency as evidenced during COVID-19 when many issuing agencies were closed and transportation services suspended. The use of paper when digital means are available is also not environmentally friendly.

5. Countries should strive to implement paperless public policies, including electronic process, and the elimination of wet signatures:

    - Wet signatures are an anachronism in the 21st Century. They are unnecessarily cumbersome, time-consuming and costly to obtain during normal times, and often impossible to secure during times of emergency as evidenced during COVID-19 when many consulates and NRAs were closed.

6. As a priority, countries should implement transitional measures so that submissions of electronic and paper legal documents are accepted under the conditions outlined in this paper. This is crucial as the procedures required to enact the requisite and definitive policy changes may depend on inter-ministerial requirements or legislation and not solely on the medical device regulatory authority. This will allow the gradual transition of technological

advance and, in this way, updated medical devices would be allowed to enter the countries according to technological and scientific advance.

Part III

Summary of the main requirements and legal backgrounds of select Latin American countries in relation to the presentation of Certificates of Free Sale / Certificates of Foreign Government to register and market imported medical devices.

(Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Chile, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay)

Country	Requirements	Legal Reference	Legal text
Argentina	CFS + Apostille/Legalization + sworn translation	Disposición 5267/2006, Art. 5º. Disposición 9688/2019, Art. 32.	Applications for registration in the Register of Producers and Medical Technology Products of Class I, II, III and IV medical devices must be accompanied by the following documentation: (d) For imported medical products: authenticated copy of **the proof of registration or certificate of free marketing or equivalent document issued by the competent authority, in the country where the medical product is manufactured and/or marketed**. This document must be legalized in accordance with the Consular Regulations or by Hague Apostille. If they are in a language other than Spanish, they must be accompanied by the respective translation made by a registered public translator and duly legalized by the Association of Sworn Translators. In this case, the interested party must present the current **official certification (Certificate of Free Sale (CLV) containing the data to be registered) issued by said competent authority that demonstrates that the medical product is authorized and marketed in that country, with a validity not exceeding 24 (twenty-four) months of its issuance or if it were described in said document according to the term established therein.** This document must be legalized in accordance with the Consular Regulations or by Hague Apostille. If it is in a language other than Spanish, it must be accompanied by the respective translation carried

			out by a registered sworn translator duly legalized by the Association of Sworn Translators.
Bolivia	CFG/CFS + Notarization/ apostille and sworn translation	Ministry Disposition 0010 of 17012003. Art 2.3.2	2.3.2 Certificate of Free Sale: In the case of imported products, the medical device certificate must be presented, stating that the product in question is duly authorized in the country of origin. The certificate must be endorsed by the competent National Health Authority and legalized by the Bolivian Consulate, taking into account the following qualifications: a) the certificate that does not indicate its validity, will have a validity according to the validity of the health registration expressed therein or two years from the date of issue, when this is not specified. b) for cases in which the country of origin does not have Bolivian consular representation, the corresponding certification from the Ministry of Foreign Affairs and Worship of Bolivia must be presented together with the original document issued by the competent health authority of the country of origin.
Brazil	CFS + Apostille and sworn translation (for documents that are not in Portuguese, English or Spanish).	In vitro diagnostics products: RDC 36/2015 Medical Device: RDC 751/22 ANVISA, article 14, IV: Art. 14	In vitro diagnostics products do not require CFS. Medical Devices Class I and II do not require CFS. Medical Device (Class II and IV): The applicant to apply for the registration of a medical device must proceed with the payment of the corresponding fee and submit the following documents to ANVISA: (IV) for imported medical devices: proof of registration or **free trade certificate or equivalent document, granted by the competent authority of the country where the medical device is manufactured and marketed or only marketed, issued in a maximum of two years - when there is no express validity indicated on the document -,** must be consularized or apostilled, and accompanied by a sworn translation when not written in Portuguese, English or Spanish.
Colombia	CFS + Apostille + sworn translation	Medical Device.	Medical Device. Sanitary registration and marketing authorization of imported medical devices. For the

		Decree 4725/2005 (Medical Device), article 29, b. In vitro. Decree 3770/2004, article 10.	expedition of health registration of medical devices or marketing permits for equipment-controlled technology biomedical products imported, the indicated procedure must be followed for the issuance of the sanitary registry, automatic sanitary registry or permission of commercialization as appropriate, taking into account the following additional requirements: […] b**) Certification from the competent authority of the country of origin stating that the product has been authorized for production or sale in the territory of the country of origin. In the event that the product to be imported is not used in the country of origin, it must be attached additionally, the certificate of a health entity stating that it is freely sold in a country of reference (European Economic Community, United States of North America, Canada, Japan and Australia), or with countries where there is a mutual recognition agreement**; Art. 44. Documents issued abroad. When the documents required by this decree are issued abroad and correspond to official information, they must be authenticated by the respective Colombian consul and by the Ministry of Foreign Affairs or, if applicable, with an Apostille stamp, in compliance with articles 65 and 259 of the Code of Civil Procedure, as the case may be and when they are not in Spanish, they will require a sworn translation. The date of issue of these documents will have the validity that the same document specifies. In the event that the document does not establish such term, it will be understood as one (1) year. In vitro. Art. 10. The health authority may require samples at any time or take them from the market for the relevant technical analysis, without the presentation of the same being a requirement for the issuance of the sanitary registration. 10.2.10 For imported products, **a certificate from the competent health authority stating that the**

			product has been authorized or not for use or production in the territory of the country of origin must be attached, indicated by the manufacturer, **and certifying that the industrial facilities and manufacturing operations conform to the quality assurance system accepted in the country and that the facilities in which the product is manufactured are subject to periodic inspections by the competent health authorities**.
Costa Rica	CFS + legalization/apostille + sworn translation	Decree N° 403902-S, RTCR 505: 2022	**Art 4.7. Certificate of free sale: It is the document issued by the health authority, which certifies that the product referred to in the certificate is authorized for sale, use and distribution in the country or region of origin.** In case of manufacture by third parties, the certificate may be issued by the health authority of the country that owns the product. Art. 10.13. All documents must be provided in Spanish, If the document is issued in different language, it must be presented with the respective translation, official or legal documents must be accompanied by the respective official translation. Art 10.15. Any certificate or official document required must be current at the time of presentation. In cases that are not indicated the validity period will be 2 years from the date of issue. Art 10.18. If the CFS is available in the authority's databases, it is allowed to provide a notarial certification of copy of the digital document. Art 10.19. The name of the manufacturer, product name and the code of the product to be registered must be clearly identifiable in the CFS. Art 10.20. When the owner and manufacturer of the product are affiliates or subsidiaries of a headquarters and the FSC does not indicate the name of the Product Owner, a signed letter must be presented by the manufacturer or headquarters

			where it declares who is the owner of the product in accordance with the definitions established in the regulation.
Chile	CFS + Apostille + translation to Spanish	Decree 825/1999 (medical device) Art. 21.	Depending on their class, medical devices must comply with the following requirements or regulatory controls and accompany the documentation indicated, where appropriate, for verification of conformity: a) Class I: [...] 6. **Certificate for export purposes granted in the country of origin, authorized by the corresponding state authority** and duly legalized, in the case of medical devices imported into Chile. Class I: includes devices that present a very low degree of risk.
Dominican Republic	CFS + Apostille + sworn translation	a) Requisitos oficiales (DGDF-RP-LI-018) para otorgamiento de registro de productos sanitarios b) Reglamento 246-06 a) Documentación Administrativa y Legal (Items 7) b) Articulo 31 número A	**Certificate of free sale of the product in force and in original, issued by the health authority of the country of origin, apostilled.**
Ecuador	CFS + Apostille + sworn translation	Medical Devices. ARCSA-DE-026-2016-YMIH. Art. 3	**Certificate of Free Sale (CFS). Official document issued by the entity or Competent National Authority or its equivalent of the state or country where the Medical Device for Human** Use is manufactured or exported, which certifies that the product meets the requirements for human use and consumption, is marketed and can be legally exported from that country. For the purposes of this standard, Export Certificates are included in this definition.

			Art. 14. The technical documents that are attached to each application will be presented in Spanish or English, and the legal documents will be presented in their official translation into Spanish and must be in all cases duly identified by their technical manager in Ecuador. Art. 16.- Requirements for imported products.- In addition to the requirements mentioned in articles 13 and 15 of these sanitary technical regulations, in order to obtain the Sanitary Registration, the requirements described below must be attached, and all documents must be duly apostilled or consularized, as appropriate: a. **Certificate of Free Sale (CLV), Export Certificate, or equivalent document in which it is declared:** Commercial name of the product, description of the product, Manufacturer / s and Owner of the product. The particularities of each country shall be considered, and the applicant shall provide sufficient information when the Free Sale Certificate (LCV) or Export Certificate does not meet the requirements referred to in this Article. b. Duly legalized authorization of the owner of the product, in which the applicant is authorized to obtain the Sanitary Registration in Ecuador, where the powers granted are clearly expressed.
EL Salvador	CFS + Apostille + sworn translation	a) RTS 11.03.02:21 b) Reglamento General de la Ley de Medicamentos a) 6.3.2. Requisitos técnicos para el trámite de registro sanitario 6.3.2.1. literal c)	a) To obtain a health registration for medical devices, the general requirements that must be submitted to the DNM are the following: c**) Certificate of Free Sale (CVL).** b) Requirements for the health registration of Medical Supplies. The requirements for health registration of Medical Supplies are as follows: 2. **Current Free Sale Certificate, duly authenticated by the corresponding authorities,** in the event that the input is imported. from another country. If the certificate covers more than one input, you can present a copy certified by a notary.

		b) Art. 24 numeral 2	
Guatemala	CFS + Apostille + sworn translation	Norma Técnica 37 Versión 5 – 2016 Artículo 5 , numeral 5.1.5 . Numeral 5.2	5.1.5 **Free Sales Certificate from the country of origin issued by the competent Health authority.** 5.2.1 When the original is mentioned, it can be replaced by a notarized photocopy. 5.2.2 The documents must be current on the day they are presented at the window 5.2.3 All documents must be legible 5.2.4 Those documents issued abroad must comply with the legal requirements and the requirements requested by the health authority, so that they are valid in Guatemala. 5.2.5 Writings in a language other than Spanish must be translated by a sworn translator authorized in the Republic of Guatemala. 5.2.6 Documents presented without an expiration date will be accepted for a maximum of two years from their date of issue.
Honduras	CFS (CFG)	Sanitary Registration requirements. https://arsa.gob.hn/requisitos-registro-sanitario/ Requirement No. 6	**6. Free Sale Certificate for imported products** Note. Current requirements do not specify any legalization requirement.
Mexico	CFS /CFG + Apostille + Sworn translation (for documents that are not in English or Spanish)	Medical Device and Invitro. Ley General de Salud, Art 222. Art. 376 and COFEPRIS web page. Reglamento de Insumos para la Salud, Art. 153. Suplemento para	Ley General de Salud, Art. 222. The Ministry of Health shall only grant the corresponding authorization to medicines, when it is demonstrated that these, their production processes and the substances they contain meet the required safety, efficacy and quality characteristics, which complies with the provisions of this Law and other general provisions, and will take into account, where appropriate, the provisions of Article 428 of this Law. For the granting of sanitary registration to any medicine, compliance with good manufacturing practices and the production process of the medicine as well as

		dispositivos Médicos de la FEUM 5.0	the certification of its active ingredients will be previously verified. The verifications shall be carried out by the Secretariat or its authorized third parties or, if applicable, **the respective certificate issued by the competent authority of the country of origin shall be recognized**, provided that there are recognition agreements in this matter between the competent authorities of both countries. Art. 376.- It is required a sanitary registration for medicines, […] medical devices except the ones identified as low risk […]. COFEPRIS web page: **Sanitary Registration of imported medical devices: Documents: […] Free Sale Certificate issued by the regulatory authority at the country of origin (Original)** Reglamento de Insumos para la Salud: Art. 153 […] Documents issued by authorities at other countries should be apostilled or legalized; in such a case when they are issued in a language different from Spanish or English, they should include its translation, produced by a legal translator which holds a professional license which supports such activity.
Nicaragua	CFS + Apostille + sworn translation	Anexo II de Resolución Administrativa N° 02/2020 Guie Pré-Evaluación de expedientes para trámite de registro de dispositivos médicos.	To Submit a Certificate of Free Sale issued in the country of origin of the product or by a Level IV Reference Authority, in original or reasoned copy, current, in Spanish or accompanied by its respective translation, apostilled or Consularized and Legalized. (The mandatory FDA* Certificate is applicable only to devices manufactured at the United States)
Panama	CFS (CFG) + Legalization + sworn translation, electronic methods are accepted.	Executive Decree 490, article 10, article 35	10. Free Sale Certificate: Document issued by the health authority of the country of origin, which indicates that the medical device is registered and that its sale for human consumption is legally authorized in that country.

Paraguay	CFS + Apostille + sworn translation	Decree 5.939/2005 (Res. GMC 40/00):	3. Procedures for Registration. 5. Manufacturers or importers to request the registration of medical products falling under classes II, III and IV, must submit to the competent authority, the following documents: d) **For imported medical products, proof of registration or free trade certificate or equivalent document, granted by the competent authority of countries** where the medical product is manufactured and / or marketed.
Peru	CFS + legalization + sworn translation	Supreme Decree Nº 016-2011-SA, Art. 21.	**The certificate of pharmaceutical product, certificate of free commercialization or document that takes its place for products or devices issued by the competent authority of the country of origin or exporter** other than the one that appears in said list is considered valid, provided that it has the legalization of the Peruvian consulate of the place or of the office that takes its place or of the embassy of the exporting country or country of origin, domiciled in Peru, which certifies that it is the competent authority.
Uruguay	CFS + Apostille + sworn translation	Decree 428/2022 (Resolution GMC N° 25/21)	6. In order to apply for registration of medical devices, manufacturers or importers (applicants) must submit the following documents to the competent health authority: (d) in the case of imported medical devices, **proof of registration or certificate of free marketing or equivalent document issued by the competent authority of the country where the medical device is manufactured and/or placed on the market**; with up to two (2) years from its issuance when there is no validity explicitly indicated in the document, and the document must be legalized or apostilled and accompanied by the corresponding translation.