CFG / FSC Apostille

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE

MEDICAL TECHNOLOGY SECTOR

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Working Group:
CFG & FSC - Apostille

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Strategy to simplify or eliminate the requirement

One standard, one test, accepted everywhere
for any medical technology scope

– EXECUTIVE COMMITTEE

Main Objective

Develop strategies to work with LATAM regulators to:

- Accept electronic CFG/FSC (document and apostille);
- Remove the requirement (when possible).

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White Paper – CFG / CFS

- Education: It explains the purpose, definitions, and requirements of CFS/CFG, giving to all stakeholders a common foundation of knowledge.
- Promotes regulatory convergence: It provides a common understanding of CFS/ CFG helping align practices across Latin American countries.
- Drives modernization: It advocates for digital, streamlined certificate processes that improve efficiency and accelerate patient access to medical technologies
- Regional Overview: Summary of the key requirements and legal backgrounds for the main countries of Latin America region.

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.

memo_CFG_CFS_v8-Final.pdf

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Milestones Achieved

1- Engagement with Local Trade associations and Authorities

- Reinforcing IACRC Position Paper on eCFG/CFS Acceptance
- Share practices from countries that eliminated CFG/CFS requirements without compromising safety or regulatory compliance.
  - Brazil: IVD and lower risk classification.
  - EUA / Europe
- Demonstrate the effectiveness of digital tools in ensuring regulatory compliance

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Milestones Achieved

2- Creation of a detailed draft Coalition Work Instruction (WI) showing how to find a product approved in regulators website for the countries:
USA, Japan, Australia, Brazil, and Canada

- The ability to consult regulators' databases ensures:

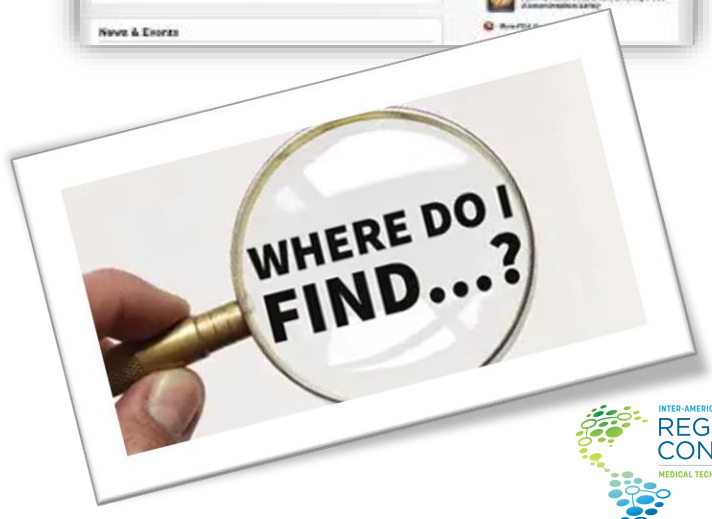
✅ The information comes directly from the competent authority.

✅ It is not necessary to request and wait for CFG/CFS documents.

✅ Multiple jurisdictions offer similar online tools.

✅ All stakeholders can confirm compliance in real time / one single source of data.

The WI highlights that regulators themselves are the most reliable source of truth for medical device approvals, and that modern online systems make CFG/CFS unnecessary for verifying product status.



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Ongoing and Future Effort

Remove CFG/CFS from registration requirements for imported medical devices:

- Authorities could rely on alternative documents.
- Technical dossiers are more aligned with IMDRF formats.
- Certification of Good Manufacturing Practices (CBPF, MDSAP).
- Adoption of **Reliance** mechanisms

    Acceptance of regulatory decisions from trusted authorities *without requiring CFG/CFS*.

Benefits of Change

- Faster patient access to innovative medical technologies worldwide.
- Reduced administrative burden for companies and regulators.
- Stronger alignment with international harmonization efforts (IMDRF, MDSAP).
- Improved competitiveness and reduced trade barriers.

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THANK YOU

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IACRC Position on CFG/CFS Acceptance

- **Acceptance of Electronic Certificates**: Countries requiring CFS/CFG should accept official electronic formats without Apostille or legalization requirements.
- **Removal of CFS/CFG Requirement**: authorities should eliminate the need for CFS/CFG if the medical device (MD) or in vitro diagnostic (IVD) is approved by internationally recognized regulatory bodies or exported to countries like the U.S. and Brazil that do not always require these certificates.

Rationale

- **Lack of Data:** No public data shows that Apostille requirements reduce falsified documents.
- **No Regulatory Impact Assessment (RIA):** No RIA conducted on the necessity of CFS/CFG. Apostille is not risk-based and modern digital tools offer better security.
- **Trust in NRAs:** Documents from trusted NRAs like FDA and ANVISA do not need further authentication.
- **Bottleneck:** CFG/CFS issuance and legalization can take weeks/months, delaying market authorization.

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Challenges –CFG / CFS

- **Legal and Regulatory Variations:**

Different countries have varying legal requirements and standards for accepting these certificates.

- **Authentication and Verification:**

Ensuring the authenticity of these certificates is crucial. Some countries require extensive verification processes to confirm that the documents are genuine and not forged.

- **Harmonization of Standards**:

There is a need for international harmonization of standards and procedures to simplify the acceptance process. This involves cooperation between various regulatory bodies to establish common guidelines

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Next steps…

Case Studies

Collect and present data showing that CFG/CFS requirements do not significantly reduce the risk of falsified documents.

Share practices from countries that eliminated CFG/CFS requirements without compromising safety or regulatory compliance.

Engage with Stakeholders

Partnership with local Trade associations to collaborate with industry to create a unified voice

Leverage Technology / Education

Demonstrate the effectiveness of digital tools in ensuring regulatory compliance

Implement pilot programs to show the feasibility of eliminating CFG/CFS requirements

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Next steps…

Regulator	Requirement of CGF /CFS	IMDRF Principle Removal	
ANVISA – Brazil	Required for class III and IV	GRRP – N47 Reliance on trusted regulators	
China – NMPA	Required for Imported products		
Mexico	All imported devices		

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Next steps…

Regulator /Region	Requirement of CGF /CFS	Products	Regulatory Reference
ANVISA – Brazil	Yes	Class III and IV	RDC 751/2022
Argentina – ANMAT	Yes	All medical devices	Mercosul requires documents form EU, USA, Canada, Japan or Australia. Dispo 2318/2002
Mexico – COFEPRIS	Yes	All medical devices	
Colombia – ANMAT	Yes		
Peru	Yes		

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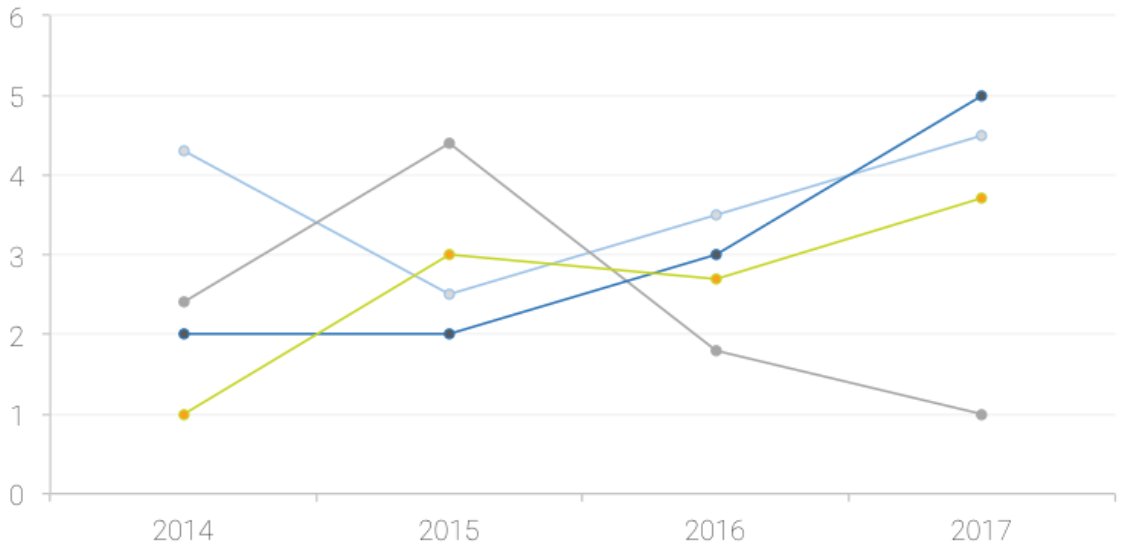

YOUR TITLE

85%

THE DATA REVEALS research subjects and data were gathered from several sources to confirm that the programs and data have been effective as shown on all projects in North and South America.

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MAP DIAGRAM SLIDE

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