IMDRF International Medical Device Regulators Forum

Dirección Nacional de Vigilancia Sanitaria – DINAVISA

DINAVISA

Regulatory Updates – IMDRF Affiliate Member

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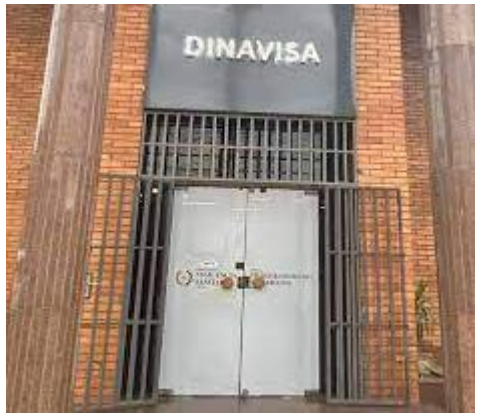
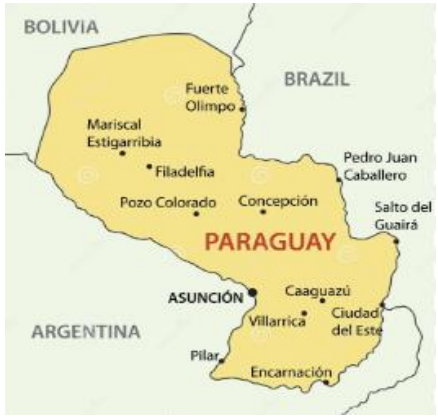
Medical and Dental Devices Directorate – DINAVISA.
Sapporo, September 2025

DINAVISA

The National Directorate of Health Surveillance (DINAVISA) is an entity with legal status under public law, with administrative autonomy, self-governance, and its own assets, as established by Law No. 6788 of August 23, 2021.





The authority responsible for developing appropriate strategies, regulating, controlling, and inspecting health products such as medicines for human use, drugs, chemicals, reagents, medical devices, and any other product used and applied in human medicine, as well as products considered cosmetics, perfumes, household and related products, food, and those products whose regulation and control are assigned to it by law, and may sanction any violations detected.

Regulation of Medical Devices - DINAVISA

Medical Devices it has an **MD INSPECTION DIRECTION**, with two departments:

- Inspection of medical devices,
- Inspection of IVD.

Two Directorates operate with the General Direction of Evaluation of Register:

- **Medical and dental device registration directorate**
- **Directorate of products for IVD**

In addition to other areas with other functions such as **Technovigilance**, etc.

Medical and dental device registration directorate:
1-Department of Dental Devices
2-Low Risk Medical Devices Department
3-Department of Moderate and High Risk Medical Devices

Directorate of products for IVD:
1-In Vitro Product Registration Department
2-Department of Validation of the performance characteristics of the product

Updates to the Medical Device Regulation - DINAVISA

❑ **September 2024 in Seattle, Washington:**
DINAVISA was accepted as an Affiliate Member of the IMDRF.

❑ **January 2024:**
A simplified procedure was established for in vitro diagnostic devices authorized and marketed in countries regulated by PAHO/WHO Reference Regulatory Authorities, the Regulatory Authorities of IMDRF member countries, and Regulatory Authorities with which bilateral agreements exist. This simplified process, under these conditions, applies to all classes of in vitro diagnostic devices. Application approval takes 15 business days.

Updates to the Medical Device Regulation - DINAVISA

❑ September 2024

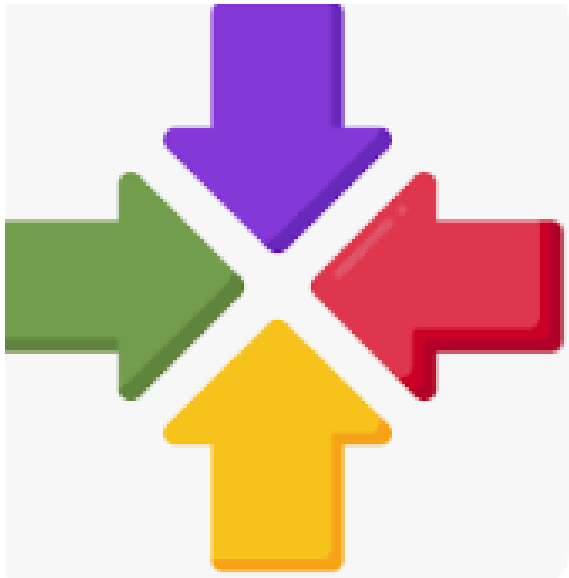
✓ A simplified process is in place for granting marketing authorizations for Class II, III, and IV medical devices (excluding IVDs) authorized by Strict Regulatory Authorities (ARES) and Reference Regulatory Authorities with the highest level of maturity according to the WHO. In the pre-marketing authorization evaluation process, a minimum number of the required documents are reviewed, as long as the conditions do not differ from those authorized by the aforementioned Regulatory Authorities. These documents are: Letter of Representation, Certificate of Free Sale or Sanitary Registration of the product, Label/Sticker/IFU. The simplified process significantly reduces the time involved in the marketing authorization process for medical devices.

✓ Class I medical devices are issued by Mandatory Health Notification, which is an automatic process and by sworn declaration of the applicant.

Regulatory Convergence:

DINAVISA constantly reviews its standards and other international standards with the goal of adopting them and thereby harmonizing regulatory requirements and approaches across different countries and regions.

This represents an important form of regulatory cooperation that enables enhanced cooperation and collaboration among regulatory authorities.

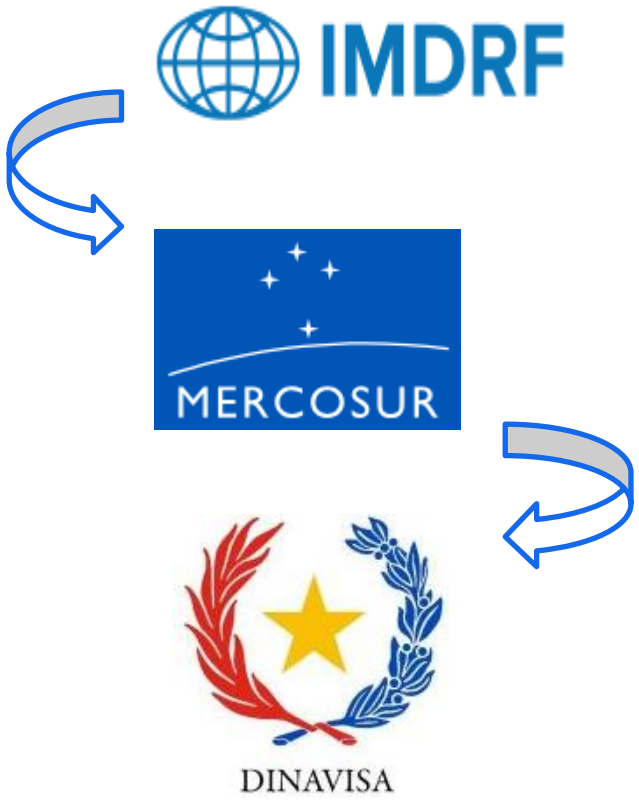


Regulatory Confidence:

DINAVISA continues to work on the COLLABORATIVE REGULATORY APPROACH, implementing simplified and agile processes by relying on regulatory decisions from other reference authorities to accelerate the marketing authorization of medical devices, improving efficiency and access to medical devices without compromising the rigor of the regulatory process. This also allows it to concentrate its resources on specific activities to strengthen public health systems.

Implementation of IMDRF documents:

As a member of MERCOSUR, DINAVISA actively participates in the technical meetings of the Medical Products Subcommittee (SCOPROME), where MERCOSUR Resolutions are updated and new Resolutions are developed that adopt the concepts and criteria established in the IMDRF working documents.



Implementation of IMDRF documents:

Some of these Resolutions approved and published by MERCOSUR are:

- ***GMC Resolution No. 25/2021 "MERCOSUR TECHNICAL REGULATION FOR THE REGISTRATION OF MEDICAL PRODUCTS (REPEAL OF GMC RESOLUTION No. 40/00)"***

In the development of the aforementioned Resolution, IMDRF documents were used as a reference. Some of these are:

- ✓ IMDRF/SaMD WG/N10FINAL:2013 Title: Software as a Medical Device (SaMD): Key Definitions.
- ✓ IMDRF/SaMD WG/N12FINAL:2014 Title: "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations.
- ✓ IMDRF/RPS WG/N19 FINAL:2016 Title: Common Data Elements for Medical Device Identification.

Implementation of IMDRF documents:

Some of these Resolutions approved and published by MERCOSUR are:

- ***GMC Resolution No. 07/24 "MERCOSUR TECHNICAL REGULATION ESSENTIAL REQUIREMENTS FOR SAFETY AND PERFORMANCE OF MEDICAL PRODUCTS AND MEDICAL PRODUCTS FOR IN VITRO DIAGNOSTICS (REPEAL OF GMC RESOLUTION No. 72/98)" which has as Reference the document:***

- ✓ Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018)

Implementation of IMDRF documents:

Draft regulations under development within the scope of MERCOSUR:

- ***Customized Medical Devices.***

This project in development has the following documents as reference:

- ✓ IMDRF/PMD WG/N49 FINAL:2018). Title: Definitions for Personalized Medical Devices
- ✓ (IMDRF/PMD WG/N74 FINAL: 2023). Tittle: Personalized Medical Devices – Production Verification and Validation.

Implementation of IMDRF documents:

Draft regulations under development at DINAVISA, which aims to adopt the concepts and criteria of IMDRF documents:

- Unique Device Identification (UDI)

Benefits of participating as an IMDRF Affiliate Member:

- Regulatory Convergence
- Strengthening the regulatory system
- Facilitation of information exchange between regulatory authorities
- Access to high-level training
- Participation in IMDRF working groups
- Regional Positioning
- Promotion of innovation and patient access to safe and effective devices

Challenges encountered:

- Language
- Active participation in working groups
- Constant technical development

IMDRF International Medical Device Regulators Forum

Thank you

DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

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