DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY | PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

Regulatory Framework for *In Vitro* Diagnostic Devices in Paraguay

Implementation of the First Regulations for IVD

Mexico, 2026

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➢ Institutional Development of IVD Regulation in Paraguay

Before 2021

- Regulation carried out by the Central Laboratory.
- No specific regulations for IVDs

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Law No. 6788/2021

- Regulatory powers of DINAVISA
- Inclusion of IVDs within DINAVISA's regulatory scope

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DINAVISA Resolution No. 266/22

- First Specific Regulatory Framework for IVDs
- Risk classification
- Defined requirements
- Standardized procedures

DINAVISA RESOLUTION No. 266/22
First Regulatory Framework for IVD Devices in Paraguay

➢ Main Objectives

- To establish requirements for the health registration of IVD devices.
- To define the regulatory scope of *in vitro* diagnostic devices.
- Implement a risk-based classification system.
- To establish harmonized technical and documentation requirements.
- Strengthen health surveillance and control activities.

Effective date: August 31, 2022

A regulatory milestone that laid the foundation for Paraguay's current IVD regulatory system

"Sesquicentenario de la Epopeya Nacional: 1864 – 1870"

Poder Ejecutivo
Dirección Nacional de Vigilancia Sanitaria
Resolución DINAVISA N° 266/2022

POR LA CUAL SE ESTABLECEN LOS CRITERIOS Y PROCEDIMIENTOS PARA LA EVALUACIÓN Y APROBACIÓN DE REGISTROS SANITARIOS DE PRODUCTOS PARA DIAGNÓSTICO DE USO *IN VITRO*

Asunción, 31 de agosto de 2022.-

VISTO:

El Memorándum DINAVISA/D.G.E y R.S N° 183/2022, por el cual la Dirección General de Evaluación y Registros Sanitario, presenta proyecto de Resolución que establece los criterios y procedimientos para la evaluación y aprobación de registros sanitarios de Productos para Diagnóstico de Uso *In vitro*; y

CONSIDERANDO:

Que, la Constitución Nacional en su Artículo 72; *Del Control de Calidad,* establece: *"El Estado velará por el control de calidad de los productos alimenticios, químicos, farmacéuticos y biológicos, en las etapas de producción, importación y comercialización"*.

➢ Scope of the Regulation

- Reagents
- Calibrators and Control Materials
- Instruments, Equipment, and Systems
- Sample Collectors

Article 2 – DINAVISA Resolution No. 266/22

This regulation covers products intended for the testing of human samples for diagnostic, monitoring, prognosis, or clinical decision-making purposes.

➢ Risk-Based Classification

- Class I – Low risk
- Class II – Moderate risk
- Class III – High risk
- Class IV – Very high risk

➢ Key General Requirements

- Administrative:

✓ Payment of the fee
✓ RUE
✓ Power of Attorney/Letter of Representation
✓ Certificate of Free Sale

- Technical:

✓ Labeling and IFU
✓ Performance Evidence
✓ Certificate of Conformity
✓ Stability Study

➢ Established Regulatory Deadlines

REGULATORY ASSESSMENT DEADLINES

DINAVISA Resolution N°266/22

Regulatory criteria	Deadline
Products that are manufactured in countries included in Annex 1 (Reference Regulatory Authorities)	**30 business days**
Products that are manufactured outside Annex 1, with Free Sales Certificate (FSC) issued by a Reference Regulatory Authority	**45 business days**
Products that are manufactured outside Annex 1, without regulatory backing from a Reference Regulatory Authority	**120 business days**

➢ From Establishing the Regulatory Framework to Implementing Reliance

2021

🏛 Law No. 6788

DINAVISA assumes regulatory authority over IVD devices.

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2022

📄 DINAVISA Resolution No. 266/22

The first specific regulatory framework for IVDs enters into force.

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2022–2026

📈 Results observed

•2,252 sanitary registrations approved to date

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2024

🌐 DINAVISA Resolution No. 44/24

Inclusion of Reliance for IVD.

➢ Challenges and Future Prospects

- Strengthening regulatory capacity.
- Consolidation of post-registration activities.
- International regulatory harmonization.
- Implementation of mechanisms for evaluating the performance of IVD devices.

➢ Conclusions

• DINAVISA Resolution No. 266/22 established the first specific regulatory framework for IVD products in Paraguay.

• It enabled the implementation of harmonized procedures and a risk-based classification system, in line with international regulatory trends.

• It provided a clear regulatory framework for the evaluation, registration, and health oversight of these products.

• It laid the groundwork for the incorporation of new regulatory tools, including reliance mechanisms and other regulatory convergence initiatives.

DINAVISA In Vitro Diagnostics Team

Gracias • Aguyje • Thank you