



INSTITUTO NACIONAL DE
**TECNOLOGÍA,
NORMALIZACIÓN Y
METROLOGÍA**

INTN and Medical Devices

**Contributing to the Strengthening of Quality in the
Regulation of Medical Devices in Paraguay**

Introduction

Strengthening national medical device regulatory systems is vital for patient safety.

- **Quality infrastructure ensures technical standards and traceability.**
- **The INTN has the technical expertise to lead this effort.**
- **Promote international regulatory convergence.**

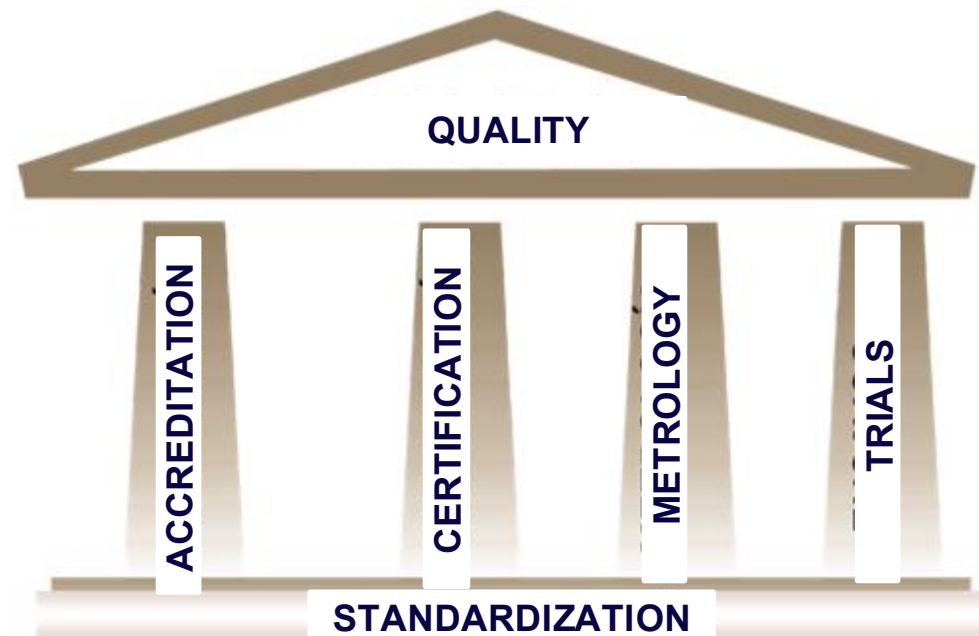


Institutional Framework

**Established by Law No. 862/63 and
reorganized by Law No. 2575/2005.**

The INTN is responsible for:

- National standardization.
- Scientific, industrial, and legal metrology.
- Conformity assessment.
- Technological research.



Standardization in Paraguay

National Standardization Body (NSB)



INTN, through the NSB, coordinates the development, adoption, review, and updating of standards through:

- More than 70 active technical committees.
- Dynamic multisectoral participation.
- Adoption of international standards (ISO).

Strategic Opportunity

Creation of the **National Technical Committee on Medical Devices** (mirroring ISO/TC 210) to:

- Participate in global technical analysis.
- Promote accelerated national adoption.
- Build specialized capacity.



International Participation

Organization	INTN Role	Category
ISO	Standardization	Corresponding Member
IEC	Electrotechnical	Corresponding Member
COPANT	Regional	Full Member
AMN	Mercosur	Full Member



International Participation

Organization	INTN Role	Category
BIPM	Weights and Measures	Member State
SIM	International System of Metrology	Member
OIML	International System of Legal Metrology	Member State

Applied Metrology

- ✓ **Safety:** Vital to the reliability of clinical measurements.
- ✓ **Priority Instruments:** Sphygmomanometers, thermometers, and balances.
- ✓ **OIML International Standards:** R 76, R 148, R 149.



Clinical Thermometers

The INTN performs:

- Type approval;
- Initial verification prior to commercialization and market release;

Statistical data (2023–2026)

- More than 10 registered importers;
- More than 20 identified brands;
- more than 600,000 units imported.



Sphygmomanometers

The INTN performs:

- Type approval certification;
- Registration of manufacturers and importers.

Statistical data (2025–2026)

- 17 registered importers;
- more than 58,000 units imported.



Scales Used in Healthcare Facilities

The INTN performs:

- Type approval certification;
- Registration of manufacturers and importers.

Statistical data (2023–2026)

- 3 identified importers;
- approximately 1,238 pieces of equipment registered.



Key Challenges

Updating
technical
standards and
regulations.

Strengthening
laboratories

Institutional
coordination

Financial
sustainability



International Cooperation

- Specialized training.
- Exchange of experts and experiences.
- Strengthening of infrastructure and laboratories.
- Development of a National Quality Program for Medical Devices.



Roadmap

1

Stakeholders

2

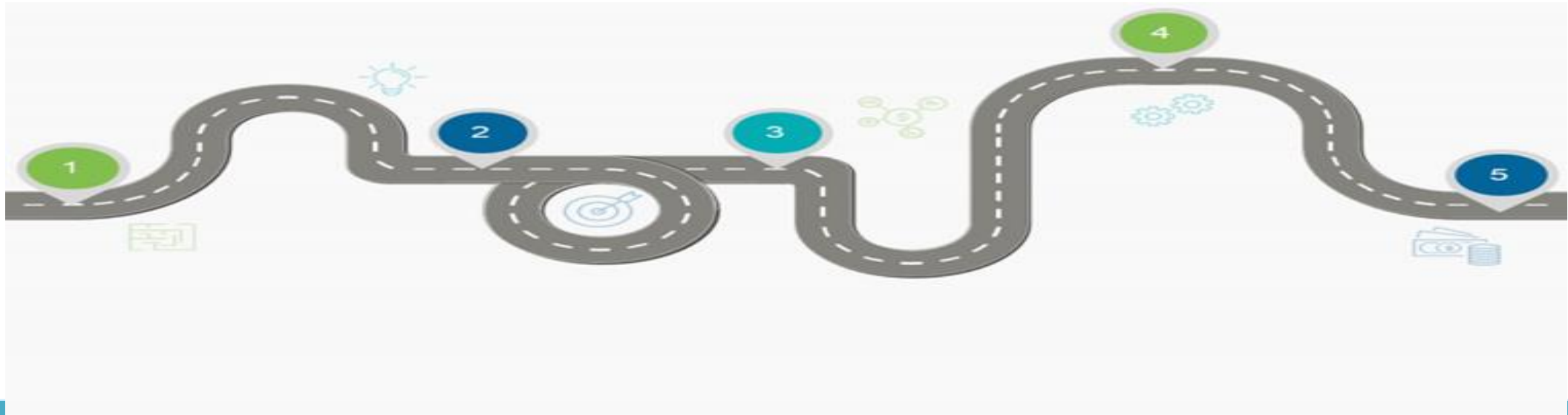
Committee

3

Prioritize

4

Monitor



Expected Impact

- ✓ Greater safety in medical devices.
- ✓ Reduced risks in measurements.
- ✓ Greater trust in health care services.
- ✓ Optimization of public resources.





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Final Reflection

Strengthening the national quality infrastructure is key to ensuring safe and effective medical devices for the public.





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THANK YOU VERY MUCH!

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