IMDRF International Medical Device Regulators Forum

Regulatory update ANMAT – ARGENTINA
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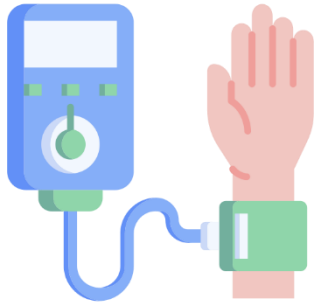
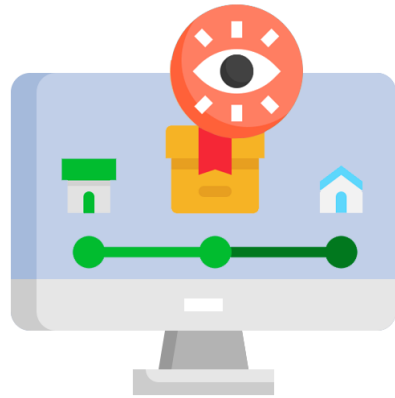
Current overview of medical device regulation in Argentina

Regulatory sequence





1) Operating licensing of companies

- 330 companies authorized per year.
- 80% initial licensing.

2) Product Registration

- 7,000 registration certificates per year.
- 70% classes I and II (low and moderate risk).

3) Post-market Surveillance

- 218 reports so far in 2025 (more than 300 per year).
- 25% are adverse events and the rest are field actions.

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Regulatory framework for the facilitation of international trade

ANMAT Regulation 2565/2025: establishes that imported medical devices may not enter the country if their expiration date is less than six months.

ANMAT Regulation 2857/2025: allows the importation for personal use of non-prescription medical devices.

ANMAT Regulation 4446/2025: ANMAT ceases to intervene in the authorization procedures for the commercial importation of medical devices classified as low and moderate risk (Classes I and II).

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Towards a new regulatory model: ex post approach

REGULATION "EX ANTE"

Before the product is approved and marketed.

VS.

REGULATION "EX POST"

After the product is already on the market and in use:

- It streamlines the import process by eliminating the need for extensive prior checks and verifications.
- Facilitates the entry of innovative products into the market.

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Argentina's participation in IMDRF

REGULATORY CONVERGENCE

- Application of the IMDRF document “Characterization Considerations for Medical Device Software and Software Specific Risk”.
- MERCOSUR working document on personalized medical devices.
- Data collection on manufacturing and importing activities of custom-made medical devices.
- “Playbook for Medical Device Regulatory Reliance Programs”.

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Challenges

A STRATEGIC LOOK TOWARDS THE FUTURE

- Ex post approach
- Strengthening post-marketing control
- Deepening reliance and convergence actions
- Progress in the implementation of SAMD and personalized MD regulations

Final Reflection