

Medical Devices Requirements

Grupo Profesional SERTERE – Regulatory Consulting in Venezuela



Requirements for Imported Medical Devices in Venezuela

Below is the complete overview of regulatory requirements in Venezuela for the sanitary registration of imported medical devices, including prerequisites, dossier documentation, labeling requirements, and estimated approval timelines.

Authorities:

Ministry of People's Power for Health (MPPS)

Autonomous Health Comptroller Service (SACS)

Sanitary Registration of Imported Medical Devices in Venezuela

1. Applicant Prerequisites

Before applying for registration:

- Importing company legally established in Venezuela
- Valid sanitary operating license
- Establishment registered with health authority
- Designated technical/health responsible person
- Representation agreement with foreign manufacturer
- Manufacturer authorization for commercialization in Venezuela

2. Administrative Documents

Administrative section of the dossier:

- Official sanitary registration application
- Importer sanitary license
- Company commercial registration
- Apostilled Power of Attorney
- Free Sale Certificate or commercialization certificate
- Proof of payment of regulatory fees
- Product holder declaration

3. Technical Requirements of the Dossier

3.1 General Device Information

- Trade name
- Models/versions
- Risk classification
- Intended use
- Principle of operation
- Full technical description

3.2 Safety and Performance

- Risk analysis (ISO 14971 or equivalent)
- Electrical safety (IEC standards)
- Performance testing
- Clinical evaluation (if applicable)
- Software validation (if applicable)

3.3 Manufacturing and Quality

- ISO 13485 certificate or equivalent
- Quality management system
- Manufacturing process description
- Finished product quality controls
- Certificates of analysis/testing

3.4 Additional Documentation

- User manual
- Installation instructions
- Maintenance/calibration procedures
- Accessories/components list

4. Food Labeling Requirements

Labeling must be in Spanish and submitted within the dossier for prior approval.

Mandatory label information:

- Device name
- Model/serial number
- Manufacturer name/address
- Importer name/address
- Country of origin
- Batch number (if applicable)
- Manufacturing/expiry date (if applicable)
- Storage conditions
- Warnings/precautions
- International symbols
- Sanitary registration number

Dossier labeling documents:

- Final label artwork
- User manual in Spanish
- Instructions for use
- Labeling compliance declaration

5. Additional Requirements

- Official Spanish translations
- Apostilled/legalized certificates
- Product samples if required
- Local technical service information

6. Timeline

Timelines may vary depending on food category and technical observations:

- Administrative review: 1 – 3 months
- Technical review: 6 – 12 months
- Additional testing: 3 – 6 months
- Total: 9 – 18 months

Average total time:

- 6 – 12 months to obtain sanitary registration.

7. Validity

- Typical validity: 5 years
- Renewal requires updated quality certificates, technical documentation, and labeling