IMDRF International Medical Device Regulators Forum | 26th Session

Salvadoran approach to basic regulatory controls and enforcement of medical devices regulations under IMDRF and WHO guidelines

Mario Vega

Head of Medical Devices Registration Unit

Sanitary Regulation Superintendency (formerly National Directorate of Medicines)

Sanitary Regulation Superintendency

DNM

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Medical devices regulatory framework

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Medical devices classification

Risk Based Classification

- **High Hazard** — D
- **Moderate-high Hazard** — C
- **Low-moderate Hazard** — B
- **Low Hazard** — A

GMDN
EMDN

IMDRF
GHTF/SG1/N77:2012
IMDRF/IVD WG/N64 FINAL: 2021
IMDRF/SaMD WG/N12FINAL:2014

Nature Based Classification

- In Vitro Diagnostic Reagents (IVD)
- Software as Medical Device (SaMD)
- Antiseptic and Disinfectant Products for Medical Use
- Other medical devices

Essential Principles of Safety and Performance

REGLAMENTO TÉCNICO SALVADOREÑO

RTS 11.03.02:21

DISPOSITIVOS MÉDICOS. REQUISITOS PARA LA REGULACIÓN SANITARIA DE DISPOSITIVOS MÉDICOS.

Correspondencia: este Reglamento Técnico Salvadoreño no tiene correspondencia con normativa internacional.

ICS 11.140.01

RTS 11.03.02:21

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UPDATING

Section 5.2.1 Medical device manufacturers shall comply with the essential principles of safety and performance established by the WHO…

Section 5.2.2 It is the manufacturers' responsibility to ensure that the medical device complies with the essential principles of safety and performance. Therefore, the DNM may verify evidence of such compliance, either before, during or after market introduction, by means of the manufacturer's technical documentation, sanitary inspections or such evaluations as it estimates necessary.

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Essential Principles Compliance

	PRINCIPLES	SRS REQUIREMENT
General essential principles	1. Medical devices should be designed and manufactured to perform as intended by the manufacturer, without compromising patient safety or the safety and health of users or other individuals.	Clinical evaluation studies / Validation report
	2. The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable.	Risk management report
	3. Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.	Clinical evaluation studies / Validation report
	4. The characteristics and performances referred to in Clauses A1, A2 and A3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device,	Technical document supporting the medical device's shelf life
	5. Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions.	Transport and storage conditions
	6. All known and foreseeable risks, and any undesirable effects, should be minimised and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.	Clinical evaluation studies / Validation report

Essential Principles Compliance

	PRINCIPLES	DNM REQUIREMENT
Design and manufacturing principles	1. Chemical, physical and biological properties	Clinical evaluation studies / Validation report and Safety data sheet
	2. Infection and microbial contamination	Sterilization certificate
	3. Medical devices incorporating a substance considered to be a medicinal product/drug	GMP certificate of the drug manufacturer
	4. Medical devices incorporating materials of biological origin	Clinical evaluation studies
	5. Environmental properties	Risk Management Report and Safety Data Sheet
	6. Devices with a diagnostic or measuring function	Certificate of Analysis or Test Report
	7. Protection against radiation	Certificate of Analysis or Test Report
	8. Medical devices that incorporate software and standalone medical device software	Software specific requirements
	9. Active medical devices and devices connected to them	Certificate of Analysis or Test Report
	10. Protection against mechanical risks	Certificate of Analysis or Test Report
	11. Protection against the risks posed to the patient or user by supplied energy or substances	Risk Management Report and Safety Data Sheet
	12. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons	Risk Management Report and Instructions for Use
	13. Label and Instructions for Use	Labeling and IFU/Manual
	14. Evaluación Clínica	Clinical evaluation studies / Validation report

Reliance

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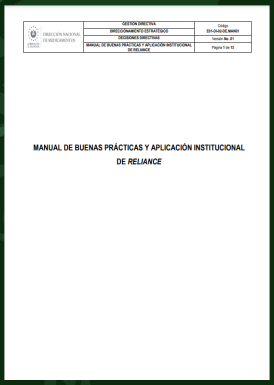
Section 6.1.4. a) The DNM may recognize and use decisions, requirements, reports or information issued by health authorities of countries whose drug regulatory agencies have been certified at level IV by PAHO/WHO, as well as those clinical trials authorized by high surveillance health agencies and by PAHO/WHO.

Annex 10. Good Reliance Practices in the regulation of medical products.



E01-DI-02-DE.MAN01 v01
Manual of good practices and institutional implementation of reliance

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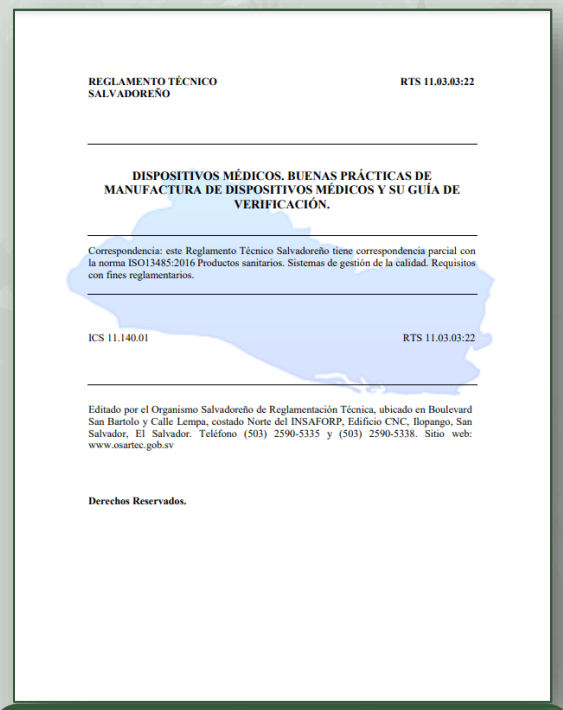
Quality Management System

In accordance with the provisions of RTS 11.03.02:21, one of the requirements for the marketing authorization of a medical device in El Salvador is that the manufacturer must comply with Good Manufacturing Practices.



REGLAMENTO TÉCNICO SALVADOREÑO — RTS 11.03.03:22

DISPOSITIVOS MÉDICOS. BUENAS PRÁCTICAS DE MANUFACTURA DE DISPOSITIVOS MÉDICOS Y SU GUÍA DE VERIFICACIÓN.

Correspondencia: este Reglamento Técnico Salvadoreño tiene correspondencia parcial con la norma ISO13485:2016 Productos sanitarios. Sistemas de gestión de la calidad. Requisitos con fines reglamentarios.

ICS 11.140.01 — RTS 11.03.03:22

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RTS 11.03.03:22 based on ISO13485:2016

MDSAP

CERTIFICATE

No. QS6 061092 0072 Rev. 01

Certificate Holder: Draeger Medical Systems, Inc.
3135 Quarry Road
Telford PA 18969
USA

Certification Mark:

Scope of Certificate: Design and Development, Production, Distribution and Servicing of Multi-Parameter Patient Monitoring Systems (ECG, Cardiac Output, EEG, Oxygen Saturation, Respiration, Gas Monitoring, Blood Pressure - Invasive and Non-Invasive, Temperature), Nerve Stimulators, Clinical Information Systems, Telemetry Systems and Transducers, Infant Incubators, Infant Radiant Warmers, Neonatal Workstations and Transport Systems, Jaundice Management Systems and Disposable and Reusable Breathing Systems for the area of Intensive and Critical Care and Neonatology

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific

5 COUNTRIES. 1 Unified Audit.

MDSAP certificate

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: APIS Assay Technologies Ltd
Citylabs 1.0, Nelson Street
Manchester
M13 9NQ
United Kingdom

Holds Certificate Number: **MD 715109**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design and development of in vitro molecular diagnostics assays for detection of biomarkers linked to various human diseases and their therapy.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-04-02
Latest Revision Date: 2020-04-02

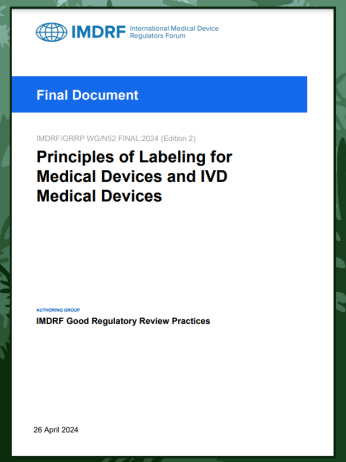
Effective Date: 2020-04-02
Expiry Date: 2023-04-01

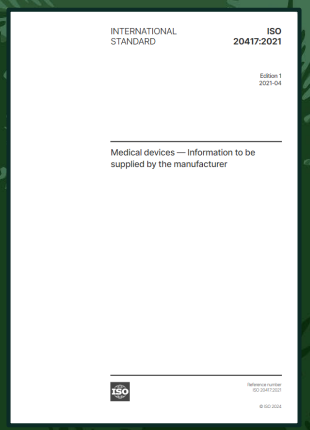
Page: 1 of 1

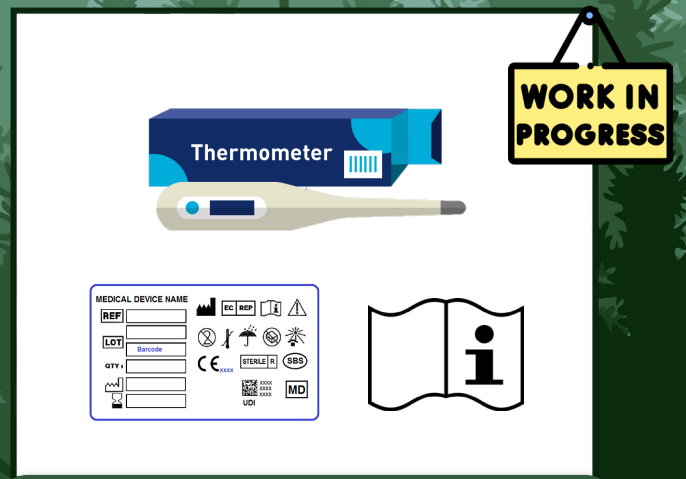
...making excellence a habit.

ISO13485:2016 certificate

Labels and Labeling







Labeling principles for medical devices in El Salvador

RTS 11.03.02:21, in section 6.3.4, stipulates some requirements for the labeling of medical devices; however, SRS is working on specific instructions aligned with IMDRF/GRRP WG/N52 FINAL:2024.

Advertising controls

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Section 6.5.4. Advertising related to medical devices must be congruent with their characteristics or specifications, according to the characteristics or specifications of the devices in accordance with the conditions of authorization granted in the granted in the sanitary registry and in no case shall it:

A. Attribute to them preventive, therapeutic, rehabilitative, or other qualities, which do not correspond to their function or intended use by the manufacturer, authorized by the DNM, in accordance with the provisions of the legislation in force.
B. Indicate or suggest that the use or consumption of a product or the rendering of a service is a determining factor to modify people's behavior.
C. Indicate or induce to believe, explicitly or implicitly, that the product contains ingredients, parts or properties of which ingredients, parts or properties of which it lacks.

Exceptional premarket situations

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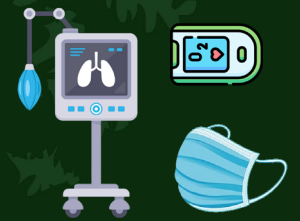
Section 6.4.2. The authorization of special import permits for medical devices may be granted in situations of public health emergency.

515 Requests

Special import authorization

2020 – 2023



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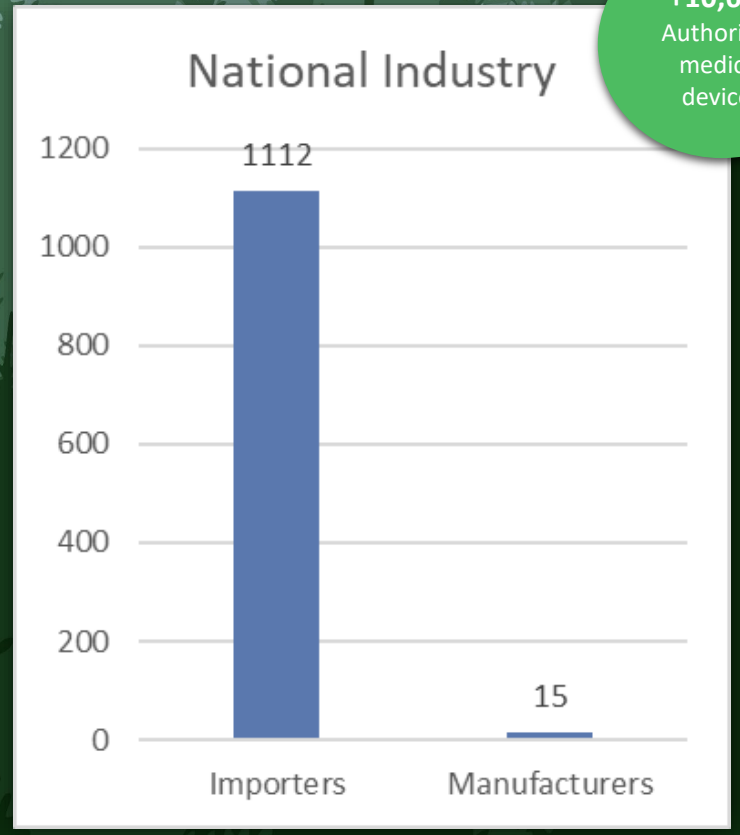
Registration of establishments

Establishments

- Manufacturers
- Importers
- Storage centers
- Conditioners
- Distributors

+10,631
Authorized medical devices

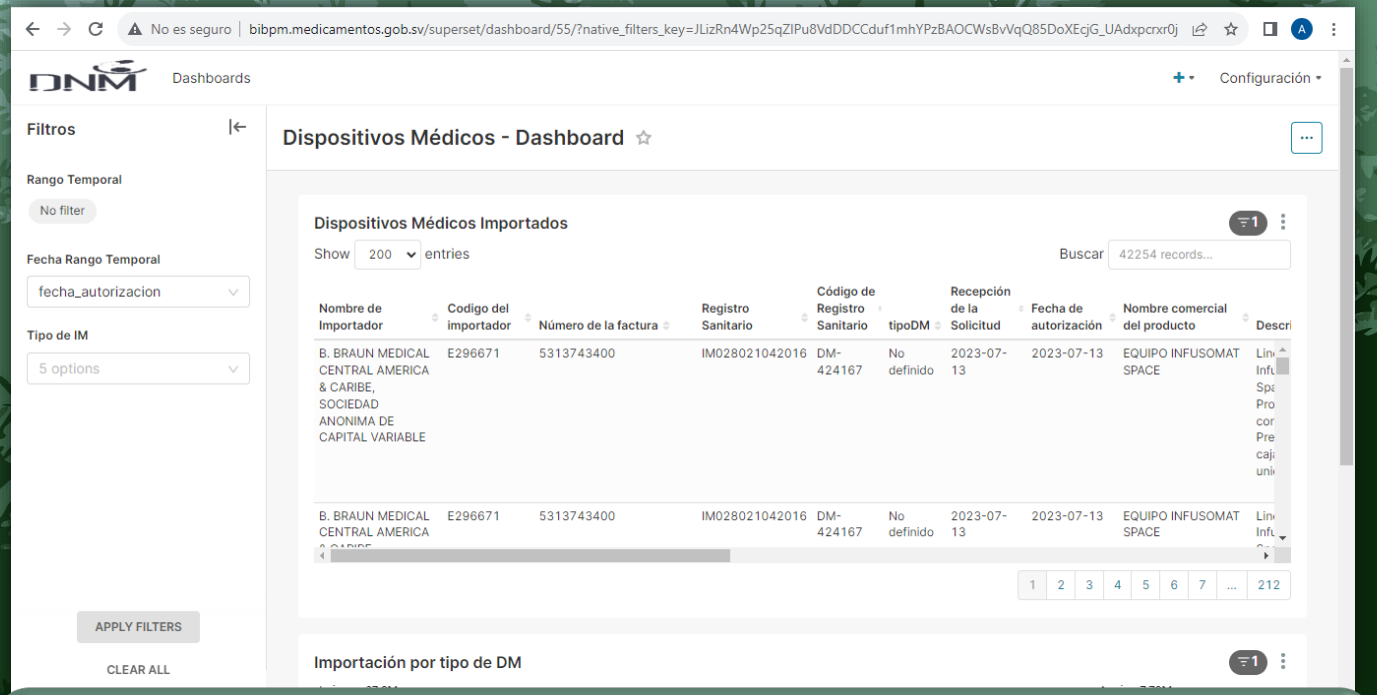


Public Consultation of Authorized Establishments

Import controls

Import control system

The SRS is part of the national Trade Facilitation Committee and works in coordination with the General Directorate of Customs.



Importer name, Importer identifier, Invoice number, Sanitary registration number, Date of application, Date of authorization, Commercial name of the product, Description, Name of the responsible professional, Reference code, Name of the holder, Product presentation, Model, Quantity, Expiration date, Manufacturer, Country of origin of the device, Lot number, among others.

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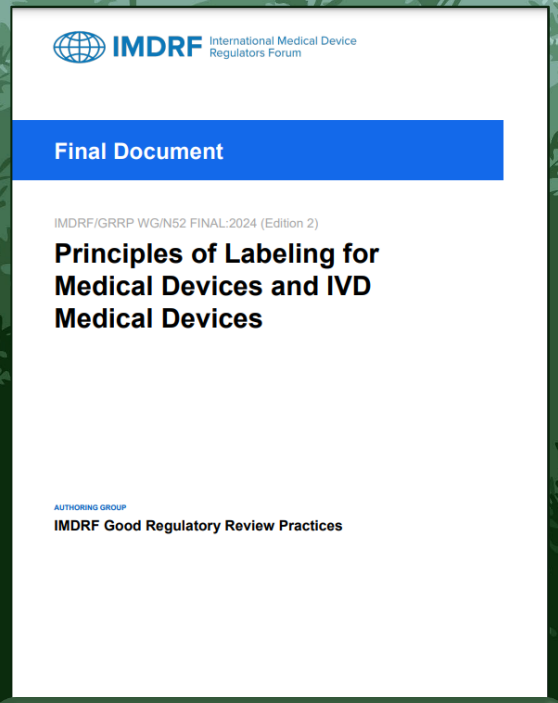
What comes next?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Final Document

IMDRF/GRRP WG/N52 FINAL:2024 (Edition 2)

Principles of Labeling for Medical Devices and IVD Medical Devices

AUTHORING GROUP

IMDRF Good Regulatory Review Practices

IMDRF/GRRP WG/N52 FINAL:2024
Principles of Labelling for Medical Devices and IVD Medical Devices


IMDRF/PMD WG/N49 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Definitions for Personalized Medical Devices

Authoring Group: IMDRF Personalized Medical Devices

Date: 18 October 2018

Yuan Lin, IMDRF Chair

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IMDRF/PMD WG/N49 FINAL:2018
Definitions for Personalized Medical Devices


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THANK YOU

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