IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

CECMED Regulatory Update

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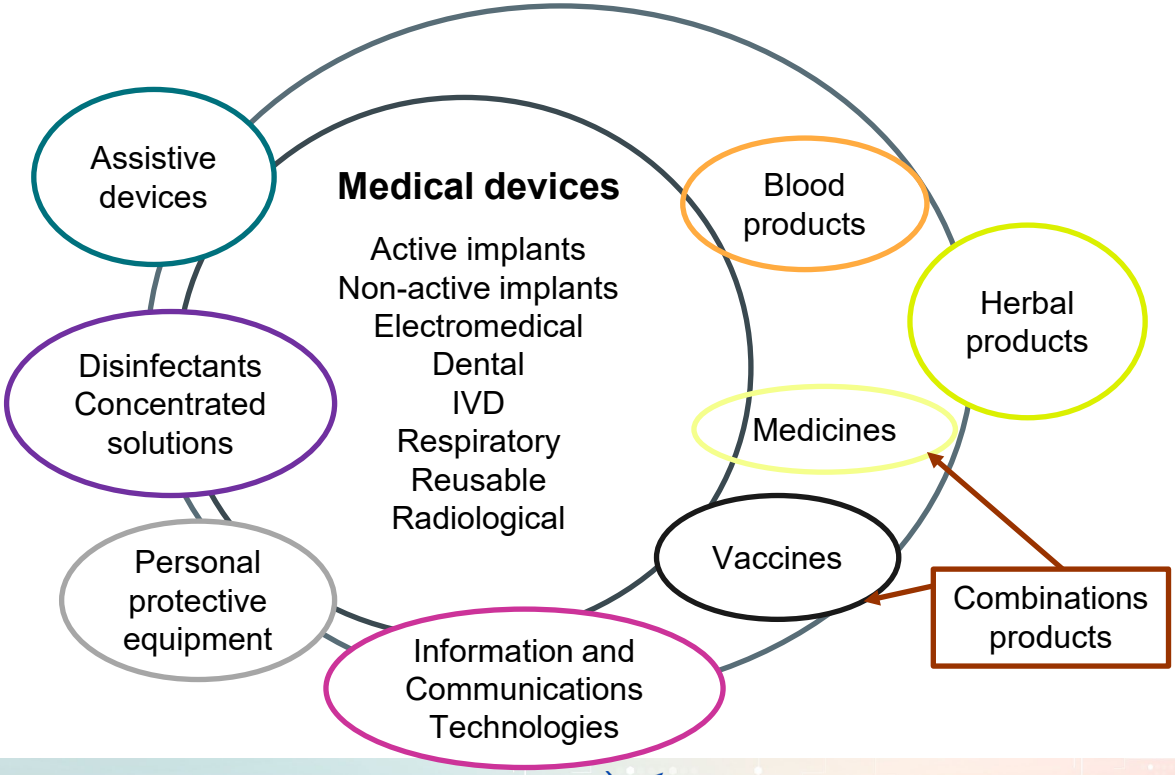
CECMED

Scope of responsibility



- ✓ **Regulatory System**
- ✓ **Regulatory Inspection/Audits**
- ✓ **Licencing/Registration Establishments**
- ✓ **Marketing Authorization**
- ✓ **Market Surveillance and Control**
- ✓ **Laboratory Testing**
- ✓ **Clinical Trials**
- ✓ **Lot Release**

Implementing IMDRF frameworks

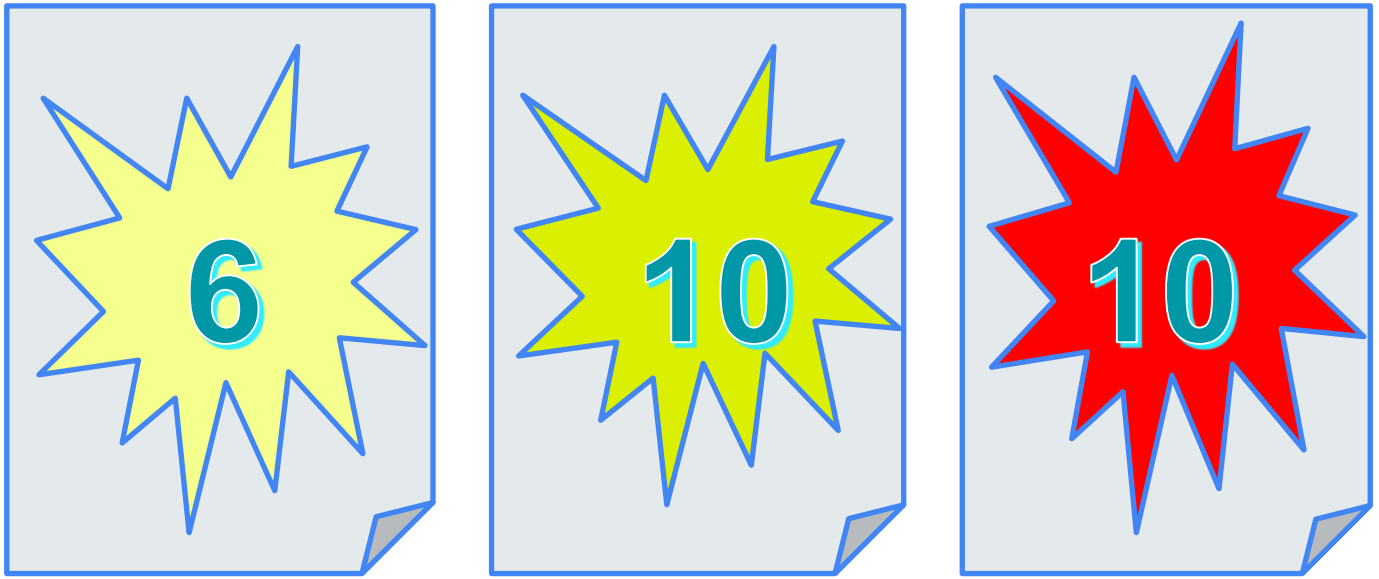
Created in **1992**, the Cuban Regulatory Program for Medical Devices, included recommendations from GHTF in the processes of conformity assessment, audits, clinical investigations and post market surveillance.

1992-2008: 7 Ministry Resolutions, 35 Regulations and 15 Guidelines published.

2008-2024: 69 Regulatory Documents published (29 updates).

74.5% of the 51 GHTF/IMDRF technical documents included in the IMDRF 2024 survey are implemmented by CECMED medical devices regulation.

New medical devices regulatory documents



2024-2026

26

Harmonization

E 119-24, Specific requirements for the sanitary registration of medical devices with a protective function
E 96-24 Requirements for Quality Management System, 4th edition
E 67-24 Authorization for clinical use of radiological medical devices. 2nd edition
Regulation for the Marketing Authorization of for In Vitro Diagnostics Medical Devices, 4th Edition
Quality Control of Instrumentation in Nuclear Medicine. National Protocol
E 102-24 Regulatory List of Recognized Standards, 19th Edition

2024

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E 127-25 Protocol for Quality Control of Magnetic Resonance Imaging Equipment
D 128-25 List of Families of In Vitro Diagnostics medical devices, 4th edition
E 129-25 Requirements for registration and re-registration of manufacturers, suppliers and importers of medical devices, 5th edition
E 130-25 Requirements for the registration and marketing authorization of software as a medical device, 5th edition
Guideline D 131-25 Classification of Non-Conformities Detected during Inspections of Good Clinical Laboratory Practices
E 132-25 CECMED's Policy for the Regulation of Medical Devices
E 133-25 Essential principles of safety and performance for medical devices, including IVDs, 2nd edition

2025

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D 60-25 Release of batches of In Vitro Diagnostics medical devices, 3rd edition
Guideline 135-25 Classification of Non-Conformities Detected during Inspections of Good Manufacturing Practices for IVDs
DM 102-25 Regulatory List of Recognized Standards, 20th edition

2025

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Labeling Principles for Medical Devices, including IVDs
Requeriments for Regulatory Work with External Experts
Conformity Assessment for Medical Devices, 2nd edition
Renewal and Modifications of Medical Devices Registry
List of Medical Devices that requiere samples assessment, 3rd edition
Promotion and Advertising of Medical Products
Principles for Postmarket Surveillance of Medical Devices, including IVDs
Minimum Instrumentation with which Nuclear Medicine services must operate in Cuba, 2nd edition
Regulatory Principles for Radiological Medical Devices
Regulatory List of Recognized Standards, 21st edition

2026

https://intranet.cecmed.local/sites/default/files/doc/gpar/base_-_intranet_2024-12-30.xlsx

Challenges

- Keeping the Regulatory Framework updated and aligned with the international technical documents.

- Implementing regulatory requeriments for UDI, Cybersecurity and Artificial Intelligence in an enviroment characterized by the lack of electric power and financial restrictions, affecting the national manufacturers and distribuitors.

Thank You!

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