HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

# 29th IMDRF 2026

## Day 2 IMDRF Stakeholder Forum | 10 March 2026

# MEDICAL DEVICES REGULATION IN COLOMBIA

**Sofia Ines del Pilar Rivera Castro**

**Specialized professional**
**Directorate of Medical Devices and Other Technologies**

**INVIMA**

# Colombian health authorities

**Ministry of Health and Social Protection:** Governing body responsible for formulating policies and issuing regulations for medical devices

It implements policies formulated by the Ministry of Health and Social Protection regarding health surveillance and quality control of medical devices.

# REGULATORY FRAMEWORK UPDATE

**Current legal framework**

2005 Decree 4725 Medical Devices

2004 Decree 3770 IVD Medical Devices

**AIN** (Regulatory impact analysis)

Gaps with international standards

**Comprehensive modification of the healthcare system**

- Referencing and Draft Amendment Proposal
- OMC Review
- Public Consultation
- Review and Consolidation – In Progress

## Scope of Application

MD + IVDMD

- Includes personalized medical devices
- Excludes custom-made medical devices
- Requirements bas… risk-based app…
- Incorporates … performance …
- Recognition … (GMP)

# Implementation of Good Regulatory Practices



IMDRF/RPS WG/N19 FINAL:2016 Common Data Elements for Medical Device Identification

IMDRF/GRRPWG/N47FINAL:2018) Essential Principles of Safety and Performance

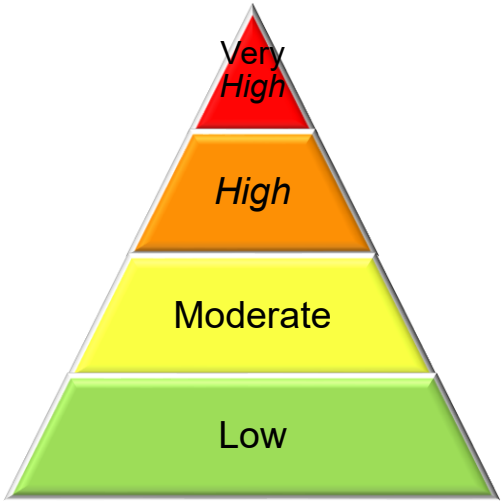
IMDRF/PMD WG/N49 FINAL:2018 Definitions for Personalized Medical Devices

Review of the Regulatory Frameworks of IMDRF Member states

WHO Regulato

- **Reliance and Recognition Mechanisms**
- **Decisions of Equivalent Foreign Regulatory Authorities**

# New Risk Classification for Medical Devices (MD) and In Vitro Diagnostic Medical Devices (IVD)




Comprehensive Evaluation

Expedited Review Process

Marketing Authorization

Marketing Authorization

Marketing Permit

Sanitary Notification

Adoption of European Union Regulations (EU) 2017/745 and (EU) 2017/746

# PARTICIPATION IN IMDRF WORKING GROUPS

**Good Regulatory Review Practices**

Develop good review practices for pre-market reviews and evaluations.

**Quality Management Systems**

Ensure alignment of IMDRF QMS and risk management documents with current international standards

# Thank You!