



IMDRF

International Medical Device
Regulators Forum

Final Document

IMDRF/MC/N84 FINAL:2026

IMDRF Document Implementation Report

AUTHORING GROUP

IMDRF Management Committee

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Preface

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Raymond Chua, IMDRF Chair

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1. Introduction

The International Medical Device Regulators Forum (IMDRF) is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to strategically accelerate international medical device regulatory convergence.

As indicated in the [IMDRF Terms of Reference](#) (ToR), IMDRF activities and initiatives may fall into several categories, one of which being technical documents created to address technical matters relating to the regulation of medical devices. The process for developing technical documents is described in the [IMDRF Standard Operating Procedure](#) (SOP) and includes seven stages. The last stage of development is implementation, which is at the discretion of each regulatory authority responsible for medical devices in the area. Each regulatory authority may need at least one year to implement a document after publication in final.

The implementation levels are defined in the IMDRF SOP and repeated below for ease of reference.

Implemented: All relevant elements, concepts and principles of the IMDRF document are followed.

Partly implemented: The IMDRF document has been implemented in a modified way that a) does not include all relevant elements, concepts and principles of the IMDRF document or b) requires application of the document for a smaller range of products than outlined in the IMDRF document.

Not applicable: The implementation of a specific IMDRF document is not applicable in a country/region.

Not implemented: The process for the implementation of the IMDRF document has not yet started or is not completed.

This document provides a report on the status of implementation of all IMDRF technical documents¹ as self-identified by IMDRF members as of the date of publication. In addition to overseeing IMDRF documents, the IMDRF Management Committee also oversees documents previously published by the GHTF. While the implementation status of GHTF documents is not included in this report, these documents are important foundational tools and continue to be managed by the IMDRF.

¹ Documents relevant to the Medical Devices Single Audit Program (MDSAP) are not included in this report. For information on the MDSAP, please see <https://www.mdsap.global/>

2. Report

Working Group	Document	Implementation Level ²		
		Implemented	Partly Implemented	Not Implemented
Software as a Medical Device (SaMD)	IMDRF/SaMD WG/N10 FINAL:2013 Software as a Medical Device (SaMD): Key Definitions	• Brazil • Canada • China • EU • Japan • Russia • Singapore • Switzerland • USA • *Argentina • *Saudi Arabia	• Australia • South Korea • UK	
	IMDRF/SaMD WG/N12 FINAL:2014 Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations	• Australia • Brazil • China • EU • Russia • Singapore • Switzerland • *Saudi Arabia	• Canada • Japan • South Korea • UK • USA • *Argentina	
	IMDRF/SaMD WG/N23 FINAL:2015	• Australia • China • EU • Russia	• Brazil • Canada • Japan • South Korea	

² Note that Official Observers are denoted with an asterisk (*) and “NA” is used to indicate when a specific IMDRF document is not applicable in a country/region.

Working Group	Document	Implementation Level ²		
		Implemented	Partly Implemented	Not Implemented
	Software as a Medical Device (SaMD): Application of Quality Management System	• Singapore • Switzerland • USA • *Saudi Arabia	• UK • *Argentina	
	IMDRF/SaMD WG/N41 FINAL:2017 Software as a Medical Device (SaMD): Clinical Evaluation	• Australia • Brazil • China • EU • Singapore • Switzerland • USA • *Saudi Arabia	• Canada • Japan • South Korea • Russia • UK	• *Argentina
	IMDRF/SaMD WG/N81 FINAL:2025 Characterization Considerations for Medical Device Software and Software-Specific Risk	• Canada • EU • Japan • South Korea • Singapore • USA	• Australia • Brazil • China • Switzerland • UK • *Saudi Arabia	• Russia • *Argentina
Unique Device Identification (UDI)	IMDRF/UDI WG/N7 FINAL:2013 UDI Guidance: Unique Device Identification (UDI) of Medical Devices	• Australia • Brazil • China • EU • Singapore • Switzerland • USA • *Saudi Arabia	• Japan • South Korea • Russia • UK	• Canada • *Argentina
	IMDRF/UDI WG/N48 FINAL: 2019	• Australia • Brazil • China • EU	• Japan • South Korea • Russia	• Canada • UK • *Argentina

Working Group	Document	Implementation Level ²		
		Implemented	Partly Implemented	Not Implemented
	Unique Device Identification System (UDI system) Application Guide	• Singapore • Switzerland • USA • *Saudi Arabia		
Regulated Products Submission (RPS)	IMDRF/RPS WG/N9 FINAL:2024 (Edition 4)	• Brazil • Canada • China • Singapore • USA • *Saudi Arabia	• South Korea • Russia	• Australia • EU • Japan • Switzerland • UK • *Argentina
	IMDRF/RPS WG/N13 FINAL:2024 (Edition 4)	• Brazil • Canada • China • Singapore • USA • *Saudi Arabia	• Australia • South Korea • Russia • *Argentina	• EU • Japan • Switzerland • UK
	IMDRF/RPS WG/N19 FINAL:2016	• Brazil • Russia • Singapore • USA	• Canada • China • South Korea • UK • *Saudi Arabia	• Australia • EU • Japan • Switzerland • *Argentina
	Common Data Elements for Medical Device Identification			
Standards- Improving the Quality of International Medical Device Standards for Regulatory Use (Standards)	IMDRF/Standards WG/N51 FINAL:2018	• Brazil • China • EU • South Korea • Russia • Singapore • Switzerland • USA	• Australia • Canada • Japan • UK • *Argentina • *Saudi Arabia	
	Optimizing Standards for Regulatory Use			

Working Group	Document	Implementation Level ²		
		Implemented	Partly Implemented	Not Implemented
Good Regulatory Review Practices (GRRP)	IMDRF/GRRP WG/N40 FINAL:2024 (Edition 2) Competence, Training, and Conduct Requirements for Regulatory Reviewers	• Australia • China • EU • South Korea • Singapore • Switzerland • *Saudi Arabia	• Japan • Russia • UK • USA • *Argentina	• Brazil • Canada
	IMDRF/GRRP WG/N47 FINAL:2024 (Edition 2) Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices	• Australia • Brazil • China • EU • Japan • South Korea • Russia • Singapore • Switzerland • *Argentina • *Saudi Arabia	• Canada • UK • USA	
	IMDRF/GRRP WG/N52 FINAL:2024 (Edition 2) Principles of Labelling for Medical Devices and IVD Medical Devices	• Australia • Brazil • China • EU • South Korea • Russia • Singapore • Switzerland	• Canada • Japan • UK • USA • *Argentina • *Saudi Arabia	
	IMDRF/GRRP WG/N59 FINAL:2024 (Edition 2) Requirements for Regulatory Authority Recognition of Conformity	• Australia • China • EU • South Korea • Russia • Switzerland	• Japan • UK • *Saudi Arabia	• Brazil^{NA} • Canada^{NA} • Singapore^{NA} • *Argentina^{NA}

Working Group	Document	Implementation Level ²		
		Implemented	Partly Implemented	Not Implemented
	Assessment Bodies Conducting Medical Device Regulatory Reviews	• USA		
	IMDRF/GRRP WG/N61 FINAL:2024 (Edition 2) Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews	• Australia • China • EU • Switzerland	• Japan • South Korea • Russia • UK • USA • *Saudi Arabia	• Brazil^{NA} • Canada^{NA} • Singapore^{NA} • *Argentina^{NA}
	IMDRF/GRRP WG/N63 FINAL:2024 (Edition 2) Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews	• Australia • China • EU • Switzerland	• Japan • South Korea • Russia • UK • USA • *Saudi Arabia	• Brazil^{NA} • Canada^{NA} • Singapore^{NA} • *Argentina^{NA}
	IMDRF/GRRP WG/N66 FINAL:2024 (Edition 2) Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews	• Australia • China • EU • Switzerland	• Japan • South Korea • Russia • UK • USA • *Saudi Arabia	• Brazil^{NA} • Canada^{NA} • Singapore^{NA} • *Argentina^{NA}
	IMDRF/GRRP WG/N71 FINAL:2024 (Edition 2)	• Australia	• South Korea	• Brazil^{NA}

Working Group	Document	Implementation Level ²		
		Implemented	Partly Implemented	Not Implemented
	Medical Device Regulatory Review Report: Guidance Regarding Information to be Included	• China • EU • Switzerland	• Russia • UK • USA	• Canada • Japan • Singapore^{NA} • *Argentina • *Saudi Arabia^{NA}
	IMDRF/GRRP WG/N89 Final:2026 Playbook for Medical Device Regulatory Reliance Programs	• Australia • Brazil • EU • Singapore	• Canada • China • Japan • South Korea • Russia • USA • *Argentina • *Saudi Arabia	• Switzerland • UK
Personalized Medical Devices (PMD)	IMDRF/PMD WG/N49 FINAL:2018 Definitions for Personalized Medical Devices	• Australia • Brazil • Canada • China • EU • Japan • Russia • Singapore • Switzerland	• South Korea • UK • USA • *Argentina • *Saudi Arabia	
	IMDRF/PMD WG/N58 FINAL:2023 (Edition 2) Personalized Medical Devices - Regulatory Pathways	• EU • Japan • Singapore • Switzerland	• Australia • Brazil • Canada • China • South Korea • Russia • UK • USA • *Argentina • *Saudi Arabia	

Working Group	Document	Implementation Level ²		
		Implemented	Partly Implemented	Not Implemented
	IMDRF/PMD WG/N74 FINAL:2023 Personalized Medical Devices - Production Verification Validation	• Singapore	• Australia • Brazil • Canada • China • EU • Japan • South Korea • Russia • Switzerland • USA	• UK • *Argentina • *Saudi Arabia
Adverse Event Terminology (AET)	IMDRF/AE WG/N43 FINAL:2021 (Edition 5) IMDRF terminologies for categorized Adverse Event Reporting (AER): Terms, terminology structure and codes	• Australia • Brazil • Canada • EU • Japan • South Korea • Singapore • Switzerland • UK • USA • *Saudi Arabia	• China • Russia • *Argentina	
	IMDRF AET WG/N85 FINAL:2024 Common Data Set for Adverse Event Data	• Brazil • Canada • EU • Switzerland • USA	• Australia • Japan • South Korea • Singapore • UK	• China • Russia • *Argentina

Working Group	Document	Implementation Level ²		
		Implemented	Partly Implemented	Not Implemented
	Exchange Between IMDRF Regulators		*Saudi Arabia	
Medical Device Clinical Evaluation (MDCE)	IMDRF MDCE WG/N55 FINAL:2019 Clinical Evidence - Key Definitions and Concepts (formerly GHTF/SG5/N1R8:2007)	- Australia - Brazil - China - EU - Japan - South Korea - Russia - Singapore - Switzerland - USA	- Canada *Saudi Arabia	- UK *Argentina
	IMDRF MDCE WG/N56 FINAL:2019 Clinical Evaluation (formerly GHTF/SG5/N2R8:2007)	- Australia - Brazil - China - EU - South Korea - Russia - Singapore - Switzerland - USA	- Canada - Japan *Saudi Arabia	- UK *Argentina
	IMDRF MDCE WG/N57 FINAL:2019 Clinical Investigation (formerly GHTF/SG5/N3:2010)	- Australia - Brazil - China - EU - Japan - South Korea - Switzerland - USA	- Canada - Russia - Singapore *Saudi Arabia	- UK *Argentina

Working Group	Document	Implementation Level ²		
		Implemented	Partly Implemented	Not Implemented
	IMDRF MDCE WG/N65 FINAL:2021 Post-Market Clinical Follow-Up Studies (formerly GHTF/SG5/N4:2010)	• Australia • EU • South Korea • Switzerland	• Canada • China • Japan • Russia • Singapore • UK • USA • *Argentina • *Saudi Arabia	• Brazil
Medical Device Cybersecurity (CYBER)	IMDRF/CYBER WG/N60 FINAL:2020 Principles and Practices for Medical Device Cybersecurity	• Australia • Brazil • Canada • EU • South Korea • Singapore • Switzerland • USA	• China • Japan • Russia • *Saudi Arabia	• UK • *Argentina
	IMDRF/CYBER WG/N70 FINAL:2023 Principles and Practices for the Cybersecurity of Legacy Medical Devices	• EU • South Korea • Switzerland • USA	• Brazil • China • Japan • Singapore	• Australia • Canada • Russia • UK • *Argentina • *Saudi Arabia
	IMDRF/CYBER WG/N73 FINAL:2023 Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity	• Canada • South Korea • USA	• Australia • Brazil • China • EU • Japan • Singapore • Switzerland	• Russia • UK • *Argentina • *Saudi Arabia

Working Group	Document	Implementation Level ²		
		Implemented	Partly Implemented	Not Implemented
Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (IVD)	IMDRF/IVD WG/N64 FINAL:2021 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (formerly GHTF/SG1/N045:2008)	• Australia • Brazil • Canada • EU • South Korea • Russia • Switzerland • *Argentina • *Saudi Arabia	• China • Japan • Singapore • USA	• UK
Artificial Intelligence (AI)	IMDRF/AIMD WG/N67 FINAL:2022 Machine Learning-enabled Medical Devices: Key Terms and Definitions	• Canada • China • EU • South Korea • Russia • Singapore • Switzerland • USA • *Saudi Arabia	• Australia • Japan	• Brazil • UK^{NA} • *Argentina
	IMDRF/AIML WG/N88 FINAL:2025 Good Machine Learning Practice for Medical Device Development: Guiding Principles	• Canada • China • EU • Japan • South Korea • Singapore • Switzerland • UK • USA	• Australia • *Saudi Arabia	• Brazil • Russia • *Argentina

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