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| Final Document |
| IMDRF/MC/N84 FINAL:2025 (Edition 2) |
| IMDRF Document Implementation Report |
| Authoring Group |
| IMDRF Management Committee |

Preface

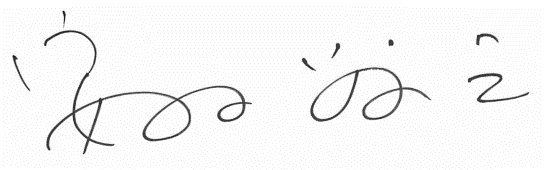
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**Naoyuki Yasuda, IMDRF Chair**

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# 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](https://www.imdrf.org/sites/default/files/2024-02/IMDRF%20MC%20N1%20Terms%20of%20Reference_2024.pdf) (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](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.imdrf.org%2Fsites%2Fdefault%2Ffiles%2F2023-10%2FIMDRF%2520Standard%2520Operating%2520Procedures%2520ext_2023%2520%2528N2%2520Edition%252010%2529_0.docx&wdOrigin=BROWSELINK) (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 documents[[1]](#footnote-2) 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.

# Report

| **Working Group** | **Document** |  | **Implementation Level[[2]](#footnote-3)** |  |
| --- | --- | --- | --- | --- |
|  |  | **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 * ​USA * ​\*Saudi Arabia | * Canada​ * Japan​ * South Korea​ * UK​ * \*Argentina​ |  |
| IMDRF/SaMD WG/N23 FINAL:2015 ​  Software as a Medical Device (SaMD): Application ​ of Quality Management System | * Australia​ * China​ * EU​ * Russia * Singapore​ * Switzerland​ * USA​ * \*Saudi Arabia | * Brazil​ * Canada​ * Japan​ * South Korea​ * UK​ | * \*Argentina​ |
| IMDRF/SaMD WG/N41FINAL:2017 ​  Software as a Medical Device (SaMD): Clinical Evaluation | * Australia * Brazil * China * EU​ * Singapore​ * Switzerland​ * USA​ * \*Saudi Arabia | * Canada​ * Japan * Russia * South Korea​ * 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 * 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 | * Brazil​ * China * EU​ * Singapore​ * Switzerland * ​USA​ | * Japan * Russia * South Korea​ * UK​ * \*Saudi Arabia | * Australia​ * Canada​ * \*Argentina​ |
| IMDRF/UDI WG/N48 FINAL: 2019 ​  Unique Device Identification System (UDI system) Application Guide | * Brazil​ * China * EU​ * Singapore​ * Switzerland * ​USA​ | * Japan * Russia * South Korea​ * \*Saudi Arabia | * Australia​ * Canada​ * UK * \*Argentina |
| **Regulated Products Submission (RPS)** | IMDRF/RPS WG/N9 FINAL:2024 (Edition 4) ​  Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)​ | * Brazil​ * Canada * China * Singapore​ * USA | * Russia * South Korea | * Australia * EU * Japan * Switzerland * UK * \*Argentina * \*Saudi ArabiaNA |
| IMDRF/RPS WG/N13 FINAL:2024 (Edition 4)​  In Vitro Diagnostic Medical Device Regulatory Submission Table of Contents (IVD ToC)​ | * Brazil * Canada * China * Singapore​ * USA | * Russia * South Korea​ * \*Argentina * \*Saudi Arabia | * Australia * EU * Japan * Switzerland * UK​ |
| IMDRF/RPS WG/N19 FINAL:2016 ​  Common Data Elements for Medical Device Identification | * Australia * Brazil​ * Russia * Singapore​ * USA | * Canada * China * South Korea​ * UK * \*Saudi Arabia | * EU * Japan * Switzerland * \*Argentina |
| **Standards- Improving the Quality of International Medical Device Standards for Regulatory Use (Standards)** | IMDRF/Standards WG/N51 FINAL:2018 ​  Optimizing Standards for Regulatory Use | * China * EU * Russia * South Korea​ * Singapore * Switzerland * USA​ | * Australia * Brazil * Canada * Japan​ * \*Argentina * \*Saudi Arabia | * UK |
| **Good Regulatory Review Practices (GRRP)** | IMDRF/GRRP WG/N40 FINAL:2024 (Edition 2) ​  Competence, Training, and Conduct Requirements for Regulatory Reviewers | * EU * Singapore​ * Switzerland | * Australia * China * Japan * Russia * South Korea * UK * USA * \*Argentina * \*Saudi Arabia | * 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 * Russia * South Korea * Singapore​ * Switzerland * \*Argentina | * Canada * UK * USA * \*Saudi Arabia |  |
| IMDRF/GRRP WG/N52  FINAL:2024 (Edition 2)  Principles of Labelling for Medical Devices and ​IVD Medical Devices | * Brazil​ * China * EU​ * Russia * South Korea * Singapore​ * Switzerland​ | * Australia * Canada * Japan * UK * USA * \*Argentina * \*Saudi Arabia |  |
| IMDRF/GRRP WG/N59 FINAL:2024 (Edition 2)  Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews | * EU * Russia * Switzerland * USA​ | * Australia​ * China * Japan * South Korea * UK | * BrazilNA * Canada​NA * SingaporeNA * \*ArgentinaNA * \*Saudi ArabiaNA |
| 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​ | * EU * Switzerland | * Australia * China * Japan * Russia * South Korea * UK * USA | * BrazilNA * Canada​NA * SingaporeNA * \*ArgentinaNA * \*Saudi ArabiaNA |
| 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​ | * EU * Switzerland​ | * Australia​ * China​ * Japan​ * Russia * South Korea​ * UK​ * USA​ | * BrazilNA * Canada​NA * SingaporeNA * \*ArgentinaNA * \*Saudi ArabiaNA |
| 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 | * EU​ * Switzerland​ | * Australia​ * China​ * Japan​ * Russia * South Korea * UK​ * USA​ | * BrazilNA * Canada​NA * SingaporeNA * \*ArgentinaNA * \*Saudi ArabiaNA |
| IMDRF/GRRP WG/N71 FIN FINAL:2024 (Edition 2) ​ ​  Medical Device Regulatory Review Report: Guidance Regarding Information to be Included | * EU​ * Switzerland | * Australia * China​ * Russia * South Korea​ * UK​ * USA​ | * BrazilNA * Canada​ * Japan * Singapore​NA * \*ArgentinaNA * \*Saudi ArabiaNA |
| **Personalized Medical Device (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​ | * Brazil​ * EU * Japan​ * Singapore​ * Switzerland | * Australia​ * Canada​ * China * Russia * South Korea​ * UK * USA * \*Argentina * \*Saudi Arabia |  |
| IMDRF/PMD WG/N74 FINAL:2023​  Personalized Medical Devices - Production Verification Validation ​ | * Singapore | * Australia​ * Brazil​ * Canada​ * China​ * EU​ * Japan​ * Russia * South Korea * ​Switzerland * USA​ | * UK * \*Argentina * \*Saudi Arabia |
| **Adverse Event Terminology (AET)** | IMDRF/AE WG/N43 FINAL:2020 (Edition 4)​  IMDRF terminologies for categorized Adverse Event Reporting (AER): Terms, terminology structure and codes | * Australia​ * Canada * EU​ * Japan * South Korea​ * Singapore​ * Switzerland​ * UK​ * USA​ * \*Saudi Arabia | * Brazil * China * Russia * \*Argentina |  |
| IMDRF AET WG/N85 FINAL:2024  Common Data Set for Adverse Event Data Exchange Between IMDRF Regulators | * Brazil * Canada * EU * Switzerland * USA | * Australia * Japan * South Korea * Singapore * UK * \*Saudi Arabia | * Russia * \*Argentina |
| **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​ * Russia * Singapore​ * Switzerland * USA​ | * Canada * South Korea​ * \*Saudi Arabia | * UK * \*Argentina |
| IMDRF MDCE WG/N56 FINAL:2019 ​  Clinical Evaluation (formerly GHTF/SG5/N2R8:2007)​ | * Australia * Brazil​ * China * EU * Russia * Singapore * Switzerland * USA​ | * Canada * Japan * South Korea​ * \*Saudi Arabia | * UK * \*Argentina |
| IMDRF MDCE WG/N57 FINAL:2019 ​  Clinical Investigation (formerly GHTF/SG5/N3:2010)​ | * Australia * Brazil​ * China * EU​ * Japan * Switzerland * USA​​ | * Canada * Russia * South Korea * Singapore * \*Saudi Arabia | * UK * \*Argentina |
| IMDRF MDCE WG/N65 FINAL:2021 ​  Post-Market Clinical Follow-Up Studies ​(formerly GHTF/SG5/N4:2010) | * Australia * EU​ * Switzerland​ | * Canada * China * Japan * Russia * South Korea​ * Singapore * USA * \*Argentina * \*Saudi Arabia | * Brazil * UK |
| **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​ | * China * Japan​ * Singapore​ | * Australia​ * Brazil​ * 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 * China * EU​ * Japan​ * Singapore​ * Switzerland​ | * Brazil​ * Russia * UK​ * \*Argentina * \*Saudi Arabia |
| **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​ * Russia * South Korea​ * 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 * Russia * South Korea * USA​ * Switzerland * \*Saudi Arabia | * ​Japan * Singapore | * Australia​ * Brazil * UKNA * \*Argentina |
| IMDRF/AIML WG/N88 FINAL:2025  Good Machine Learning Practice for Medical Device Development: Guiding Principles | * Canada * EU * Japan * South Korea * Switzerland * UK * USA | * Australia * Singapore * \*Saudi Arabia | * Brazil * Russia * \*Argentina |

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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/> [↑](#footnote-ref-2)
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. [↑](#footnote-ref-3)