DRAFT (Not for publication)

IMPLEMENTATION TABLE

Date of issue: Sep. 10, 2020

Instructions for Completing the Implementation Table.
Please choose 'FI' or 'PI' or 'NA' or 'NI' from the drop-down menu, taking into account following criteria:

FI (fully implemented): All relevant elements, concepts and principles of the IMDRF document are followed
PI (partly implemented): The IMDRF document has been implemented in a modified way, that * (see below)
NA (not applicable): The implementation of a specific IMDRF document is not applicable in a country/region
NI (not implemented): The process for the implementation of an IMDRF document has not yet started or is not completed

Working Group	No	Document name	Australia	Brazil	Canada	China	EU	Japan	S. Korea	Russia	Singapore	USA
Medical Device Single Audit Program (MDSAP)	1	IMDRF/MDSAP WG/N3 FINAL:2016 Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition	FI	FI	FI	PI	PI	FI	NA	PI	PI	FI
	2	IMDRF/MDSAP WG/N4 FINAL:2013 Competence and Training Requirements for Auditing Organizations	FI	FI	FI	PI	PI	FI	PI	PI	PI	FI
	3	IMDRF/MDSAP WG/N6 FINAL:2013 Regulatory Authority Assessor Competence and Training Requirements	PI	FI	FI	PI	PI	FI	NA	NI	PI	FI
	4	IMDRF/MDSAP WG/N11 FINAL:2014 MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization	FI	FI	FI	PI	PI	FI	NA	NI	PI	FI
	5	IMDRF/MDSAP WG/N24 FINAL:2015 Medical Device Regulatory Audit Reports	FI	FI	FI	PI	PI	FI	PI	PI	PI	FI
National Competent Authority Report (NCAR)	6	IMDRF NCAR WG/N14FINAL:2017 Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form	FI	FI	FI	PI	PI	FI	PI	NI	FI	FI
Software as a Medical Device (SaMD)	7	IMDRF/SaMD WG/N10 FINAL:2013 Software as a Medical Device (SaMD): Key Definitions	PI	NI	FI	FI	PI	FI	PI	PI	FI	FI
	8	IMDRF/SaMD WG/N12 FINAL:2014 Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations	PI	NI	PI	FI	FI	PI	PI	NI	FI	FI
	9	IMDRF/SaMD WG/N23 FINAL:2015 Software as a Medical Device (SaMD): Application of Quality Management System	FI	PI	PI	FI	PI	PI	PI	NI	FI	FI
	10	IMDRF/SaMD WG/N41FINAL:2017 Software as a Medical Device (SaMD): Clinical Evaluation	PI	NI	NI	FI	FI	PI	PI	NI	FI	FI
Unique Device Identification (UDI)	11	IMDRF/UDI WG/N7 FINAL:2013 UDI Guidance: Unique Device Identification (UDI) of Medical Devices	NI	PI	NI	FI	FI	PI	PI	NI	FI	FI
	12	IMDRF/UDI WG/N48 FINAL: 2019 Unique Device Identification System (UDI system) Application Guide	NI	NI		FI	FI	PI			PI	FI
Regulated Product Submission	13	IMDRF/RPS WG/N9 FINAL:2019 (Edition 3) Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)	PI	PI	FI	FI	NI	NI	PI	NI	FI	PI
	14	IMDRF/RPS WG/N13 FINAL:2019 (Edition 3). In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)	PI	PI	FI	FI	NI	NI	PI	NI	FI	PI

Working Group	No	Document name	Australia	Brazil	Canada	China	EU	Japan	S. Korea	Russia	Singapore	USA
(RPS)	15	IMDRF/RPS WG/N19 FINAL:2016 Common Data Elements for Medical Device Identification	PI	NI	PI	PI	NI	NI	PI	NI	FI	PI
	16	IMDRF/RPS WG/N27 FINAL:2019 Assembly and Technical Guide for IMDRF Table of Contents Submissions	PI	NI		PI	NI	NI	NA		NI	PI
Standards - Improving the quality of international medical device standards for regulatory use (Standards)	17	IMDRF/Standards WG/N51 FINAL:2018 Optimizing Standards for Regulatory Use	PI	PI	PI	FI	PI	NI	PI	NI	PI	FI
Patient Registries (Registry)	18	IMDRF/REGISTRY WG/N33FINAL:2016 Principles of International System of Registries Linked to Other Data Sources and Tools	NI	NI	NI	NI	PI	PI	NI	NI	NI	FI
	19	IMDRF/Registry WG/N42FINAL:2017 Methodological Principles in the Use of International Medical Device Registry Data	NI	NI	NI	NI	PI	PI	NI	NI	NI	FI
	20	IMDRF/Registry WG/N46 FINAL:2018 Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making	NI	NI	NI	NI	PI	PI	NI	NI	NI	FI
Good Regulatory Review Practices (GRRP)	21	IMDRF/GRRP WG/N40FINAL:2017 Competence, Training, and Conduct Requirements for Regulatory Reviewers.	PI	NI	NI	PI	PI	PI	PI	NI	FI	PI
	22	IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices	PI	PI	PI	FI	PI	FI	PI	PI	FI	PI
	23	IMDRF/GRRP WG/N52: Principles of Labelling for Medical Devices and IVD Medical Devices	PI	NI	PI	FI	FI	PI	PI	PI	FI	PI
	24	IMDRF/GRRP WG/N59 FINAL:2020 Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews	NI	NI	NI	PI	PI	PI	PI	NI	NA	FI
	25	IMDRF/GRRP WG/N61 FINAL:2020 Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews	PI	NI		PI	PI	PI			NA	PI
	26	IMDRF/GRRP WG/N63 FINAL:2020 Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews	PI	NI		PI	PI	PI			NA	PI

Working Group	No	Document name	Australia	Brazil	Canada	China	EU	Japan	S. Korea	Russia	Singapore	USA
	27	IMDRF/GRRP WG/N66 FINAL:2021 Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews				PI						
Personalized Medical Device (PMD)	28	IMDRF/PMD WG/N49 FINAL:2018 Definitions for Personalized Medical Devices	PI	FI	FI	FI	PI	FI	PI	PI	FI	PI
	29	IMDRF/PMD WG/N58 FINAL:2020 Personalized Medical Devices - Regulatory Pathways	PI	FI	NI	PI	NI	FI	PI	NI	PI	PI
Adverse Event Terminology (AE)	30	IMDRF/AE WG/N43 FINAL:2021 (Edition 5) IMDRF terminologies for categorized Adverse Event Reporting (AER):Terms, terminology structure and codes	FI	PI	PI	PI	FI	PI	PI	PI	FI	FI
Medical Device Clinical Evaluation Working Group (MDCE)	31	IMDRF MDCE WG/N55 FINAL:2019 Clinical Evidence - Key Definitions and Concepts (formerly GHTF/SG5/N1R8:2007)	NI	FI	PI	FI	PI	FI	PI	PI	FI	FI
	32	IMDRF MDCE WG/N56FINAL:2019 Clinical Evaluation (formerly GHTF/SG5/N2R8:2007)	NI	FI	PI	FI	PI	PI	PI	PI	FI	FI
	33	IMDRF MDCE WG/N57FINAL:2019 Clinical Investigation (formerly GHTF/SG5/N3:2010)	NI	FI	PI	FI	PI	FI	PI	PI	PI	FI
	34	IMDRF MDCE WG/N65FINAL:2021 Post-Marekt Clinical Follow-Up Studies (formerly GHTF/SG5/N4:2010)	NI	NI		PI	FI	PI			PI	PI
Medical Device Cybersecurity Working Group (CYBER)	35	IMDRF/CYBER WG/N60 FINAL:2020 Principles and Practices for Medical Device Cybersecurity	PI	NI	PI	PI	FI	PI	PI	NI	PI	FI
Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (IVD)	36	IMDRF/IVD WG/N64 FINAL:2021 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	FI	NI		PI	FI	PI	PI		FI	PI

* that a) incorporates additional requirements beyond those defined in the IMDRF document,
or b) does not include all relevant elements, concepts and principles of the IMDRF document,
or c) requires application of the document for a smaller range of products than outlined in the IMDRF document.

Implementation of IMDRF guidance is at the discretion of each regulatory authority responsible for public health in the area.