Tracking tool – available documents supporting IVDR/MDR implementation

Version: 14 January 2021

This tracking tool collects available information sources in one place, to support industry in transitioning to and implementing the IVDR and MDR:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, as amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions - **referenced as MDR in this document**
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU **– referenced as IVDR in this document**

This document lists not only final and published documents, but also documents that already in the drafting phase or in the pipeline (i.e., where no draft exists yet). Where possible, an estimated timing is given for finalisation of draft documents. Therefore, this document is organised in two sections:

- Part I: State of Play – Published documents*: *(new)* label refers to sources added in the last 3 months.
- Part II: Rolling Plan – Documents in the pipeline: *(newly added)* label refers to sources added in the last 3 months.

Please refer to table of contents below to quickly access the relevant sections of interest.

Note*: The referenced external sources are **European-level documents that are available on the European Commission website [such as guidance documents adopted by the Medical Device Coordination Group (MDCG)[1] or as implementation tools] or at the Competent Authorities for Medical Devices (CAMD) website. The list also includes available legal sources such as implementing or delegated acts. The other referenced sources are **MedTech Europe documents** that are available on the MedTech Europe website in the Regulatory e-Library (either external sources such as position papers, or internal sources such as guidance documents, Q&As, training materials, etc.). **Only MedTech Europe members have access to internal documents. If your organisation is a member, please ask for a login.** This tracking tool will be updated periodically. MedTech Europe's Regulatory e-Library is where the most recent and up-to-date version of the tracking tool is stored.

[1] Legally non-binding guidance documents, adopted by the Medical Device Coordination Group (MDCG) in accordance with Article 105 of Regulation 745/2017, pursue the objective of ensuring uniform application of the relevant provisions of the Regulations within the EU.

Contents

Part I: State of Play – Published documents

MDCG Working Groups					
External for public / Internal for MedTech Europe members	**Type of document**	**Source/ Owner**	**Document (title and link)**	**Date of publication**	**Applicable legislation**
Notified Bodies Oversight (NBO) (TOR and related information) (*Closed* – covers requirements set out by designating authorities specifically for Notified Bodies)					
External	Guidelines	MDCG	MDCG 2020-17 Questions and Answers related to MDCG 2020-4 *(new)*	**2020 December**	IVDR/MDR
External	Guidelines	MDCG	MDCG 2020-14 Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR)	**2020 August**	IVDR/MDR
External	Informative document	European Commission	Information on the applications for designation as a notified body	**2020 July**	IVDR/MDR
External	Guidelines	MDCG	MDCG 2020-11 Guidance on the renewal of designation and monitoring of notified bodies under Directives 90/385/EEC and 93/42/EEC to be performed in accordance with Commission Implementing Regulation (EU) 2020/666 amending Commission Implementing Regulation	**2020 May**	AIMDD/ MDD
External	Implementing regulation	European Commission	Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies	**2020 May**	AIMDD/ MDD

External	Guidelines	European Commission	Commission Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745	**2020 May**	MDR
External	Guidance	MDCG	MDCG 2020-4 Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions	**2020 April**	IVDD AIMDD/ MDD
External	Guidance	NBO	MDCG 2019-14 Explanatory note on MDR codes	**2019 December**	MDR
External	Guidance	NBO	MDCG 2019-13 Guidance on sampling of devices for the assessment of the technical documentation	**2019 December**	IVDR/MDR
External	Guidance	MDCG	MDCG 2018-8 Guidance on content of the certificates, voluntary certificate transfers	**2019 November**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-6 v2 Updated version of Questions and Answers: Requirements relating to notified bodies	**2019 October**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-12 Designating Authority's Final Assessment Form Under MDR, IVDR	**2019 October**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-10 Application of transitional provisions concerning validity of certificates issued in accordance to the directives	**2019 October**	IVDR/MDR
External	Guidance	NBOG	NBOG F 2017-8 Review of qualification for the authorisation of personnel (IVDR)	**2018 May (rev.1)**	IVDR
External	Guidance	NBOG	NBOG F 2017-7 Review of qualification for the authorisation of personnel (MDR)	**2018 May (rev.1)**	MDR
External	Template	NBOG	NBOG F 2017-6 Preliminary assessment review template (IVDR)	**2018 May (rev.1)**	IVDR
External	Template	NBOG	NBOG F 2017-5 Preliminary assessment review template (MDR)	**2018 May (rev.1)**	MDR
External	Guidance	NBOG	NBOG F 2017-4	**2018 May (rev.2)**	IVDR

			Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR)		
External	Guidance	NBOG	NBOG F 2017-3 Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR)	**2018 May (rev.2)**	MDR
External	Template	NBOG	NBOG F 2017-2 Application form to be submitted by a conformity assessment body when applying for designation as a notified body under the in vitro diagnostic devices Regulation (IVDR)	**2018 May (rev.3)**	IVDR
External	Guidance	NBOG	NBOG BPG 2017-1 Best practice guidance on designation and notification of conformity assessment bodies	**2018 February (rev.3)**	IVDR/MDR
External	Guidance	NBOG	NBOG BPG 2017-2 Best practice guidance on the information required for personnel involved in conformity assessment	**2018 February (rev.1)**	IVDR/MDR
External	Template	NBOG	NBOG F 2017-1 Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices Regulation (MDR)	**2018 February (rev.1)**	MDR
External	Handbook	NBOG	Designating Authorities Handbook (EN)		IVDR/MDR
External	Implementing Regulation	European Commission	Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the codes for the designation of notified bodies in medical devices under Regulation (EU) 2017/745 and in vitro diagnostic medical devices under Regulation (EU) 2017/746	**2017 November**	IVDR/MDR
External	Informative document	European Commission	European Commission Information note on joint assessments under the new regulations on Medical Devices	**2017 November**	IVDR/MDR

External	Link	European Commission/ Designating Member States	Official list of designated Notified Bodies under the MDR (NANDO)	Continuously updated upon new information is received from the designating authorities	MDR
External	Link	European Commission/ Designating Member States	Official list of designated Notified Bodies under the IVDR (NANDO)	Continuously updated upon new information is received from the designating authorities	IVDR
Standards (TOR) and related information					
External	Implementing Decision	European Commission	Implementing Decision M/565 on a standardisation request to CEN/CENELEC for MDR / IVDR harmonised standards *(note the request published contains errors and will be updated)* - MedTech Europe response to the draft Standardisation request	**2020 May**	IVDR/MDR
Internal	Guidance/ Position paper	MedTech Europe	Use of international generally acknowledged state-of-the-art standards in the absence of harmonised standards under the IVDR and MDR	**2020 March**	IVDR/MDR
Internal/ External	Position Paper	MedTech Europe	MedTech Europe position on the proposed draft Standardisation Request for IVDR and MDR	**2019 May**	IVDR/MDR
Clinical Investigation and Evaluation (CIE) (TOR) and related information					
External	Template	MDCG	MDCG 2020-13 Clinical Evaluation Assessment Report (CEAR) Word version	**2020 July**	MDR
External	Guidance	MDCG	MDCG 2020-10/1 Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745	**2020 May**	MDR
External	Guidance	MDCG	MDCG 2020-10/2 Clinical Investigation Summary Safety Report Form v1.0	**2020 May**	MDR

External	Template	MDCG	MDCG 2020-8 Guidance on Post-Market Clinical Follow-up (PMCF) Evaluation Report Template	**2020 April**	MDR
External	Template	MDCG	MDCG 2020-7 Guidance on Post-Market Clinical Follow-up (PMCF) Plan Template	**2020 April**	MDR
External	Guidance	MDCG	MDCG 2020-6 Guidance on Sufficient Clinical Evidence for Legacy Devices	**2020 April**	MDR
External	Guidance	MDCG	MDCG 2020-5 Guidance on Clinical Evaluation - Equivalence	**2020 April**	MDR
External	Guidance	MDCG	MDCG 2019-9 Summary of Safety and Clinical Performance - SSCP	**2019 September**	MDR
Internal	Training material	MedTech Europe	Good clinical practice ISO 14155 webinar and slides	**2019 April**	MDR
Internal	Training material	MedTech Europe	Clinical investigations and clinical evaluation webinar and slides	**2019 April**	MDR
Post-Market Surveillance and Vigilance (PMSV) (TOR) and related information					
External	Q&A	MDCG	Questions and Answers document regarding the Implementation of the new Manufacturer Incident Report (MIR) Form	**2020 May**	IVDR/MDR
External	Template	MDCG	Manufacturer Incident Reporting (MIR) template version 7.2.1	**Updated 2020 May**	IVDR/MDR
External	Template	MDCG	Manufacturer incident report for importing XML file with Adobe Professional 2020	**Updated 2020 May**	IVDR/MDR
External	Template	MDCG	New manufacturer incident report XSD files (for implementation in manufacturer' databases)	**Updated 2020 May**	IVDR/MDR
External	Guidance	MDCG	MIR Changelog file 2020	**Updated 2020 May**	IVDR/MDR
Internal	Q&A	MedTech Europe	Industry Q&A on MIR	**2020 March**	IVDR/MDR

External	Guidance	MDCG	Helptext MIR document v.7.2	**Updated 2019 September**	IVDR/MDR
Internal /External	Guidance	MedTech Europe	Vigilance guidance (industry proposal to feed into MDCG guidance)	**2019 September**	IVDR/MDR
External	Guidance	MDCG	DSVG 04 - Breast Implants vigilance reporting guidance	**2019 September**	MDR
External	Guidance	MDCG	DSVG 03 - Cardiac Implantable Electronic Devices (CIED) vigilance reporting guidance	**2019 September**	MDR
External	Guidance	MDCG	Meddev 2.12.1 rev8 Clarification document ('Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8)	**2019 July**	IVDR/MDR
External	Template	MDCG	Field Safety Notice template (for HCPs), Rev 1	**2018 October**	IVDR/MDR
External	Template	MDCG	Template for a Field Safety Notice Customer Reply Form	**2018 October**	IVDR/MDR
External	Template	MDCG	Template for a Field Safety Notice Distributor/Importer Reply Form	**2018 October**	IVDR/MDR
External	Template	MDCG	Questions and Answers to fill in the Field Safety Notice (FSN)	**2018 October**	IVDR/MDR
Internal	Training material	MedTech Europe	Overview of Post Market Surveillance in the EU - webinar and presentation	**2018 September**	IVDR/MDR
Internal	Q&A	MedTech Europe	MedTech Europe internal Q&A supporting MDR IVDR implementation – Post Market Surveillance and Vigilance	**2018 June**	IVDR/MDR
Internal	Training material	MedTech Europe	Manufacturer Incident Reporting form webinar and presentation	**2018 April**	IVDR/MDR
Internal	Guidance	MedTech Europe	Post Market Surveillance Plan - MTE one pager	**2018 April**	IVDR/MDR
Internal	Guidance	MedTech Europe	Trend Reporting - MTE one pager	**2018 April**	IVDR/MDR

External	Guidance		DSVG 01 - Cardiac ablation vigilance reporting guidance	**2016 July**	MDR
External	Guidance		DSVG 02 - Coronary stents vigilance reporting guidance	**2015 September**	MDR
Market Surveillance (TOR) and related information (Closed – for competent authorities only)					
External	Guidance	MDCG	MDCG 2019-15 - Guidance Notes for Manufacturers of Class I Medical Devices	**2019 December**	MDR
External			Joint Action on Market Surveillance of Medical Devices (JAMS)		
Borderline and Classification (B&C) (TOR) and related information					
External	Guidance	MDCG	Manual on Borderline and Classification, Version 1.22	**2019 May**	IVDR/MDR
New Technologies (TOR) and related information					
Internal	Guidance	MedTech Europe	Best Practice Guidance - How to Label IVD and Medical Device Software (MDSW)? *(new)*	**2020 October**	IVDR/MDR
External	Guidance	MDCG	MDCG 2020-1 - Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software	**2020 March**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-16 - Guidance on Cybersecurity for medical devices	**2020 January**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-11 - Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR	**2019 October**	IVDR/MDR
EUDAMED (TOR) and related information					
External	Platform for Actor registration	European Commission	Release the Actor registration module of EUDAMED allowing the Economic Operators to obtain a Single Registration Number (SRN) Official info page:	**2020 December 1**	IVDR/MDR

			https://ec.europa.eu/health/md_eudamed/actors_registration_en *(new)*		
External	Public site of EUDAMED	European Commission	The official web address of the EUDAMED public site will be: https://ec.europa.eu/tools/EUDAMED *(new)*	**2020 December 1**	IVDR/MDR
External	Restricted site of EUDAMED	European Commission	EUDAMED restricted site: https://webgate.ec.europa.eu/eudamed/landing-page#/ *(new)*	**2020 December 1**	
External	Position paper	MDCG	MDCG 2020-15 Use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States	**2020 August**	IVDR/MDR
External	Factsheet	European Commission	MDR requirements for Transparency and Public Information List of information which will be available to the public in accordance with transparency obligations / requirements once EUDAMED is fully functional	**2020 July**	MDR
External	Advocacy document	Joint industry associations	Interim measures applicable in the absence of MDR EUDAMED - Executive summary by joint industry associations	**2020 March**	IVDR/MDR
External	Advocacy document	Joint industry associations	Concerns about the delay of EUDAMED implementation - Joint industry statement	**2019 December**	IVDR/MDR
External	Informative document	European Commission	EUDAMED UDI device data dictionary V5.0	**2019 December**	IVDR/MDR
Internal	Training material	MedTech Europe	Summary of EUDAMED draft documentation – part 1 (modules covered: UDI & Device Registration; Notified Body & Certificates; Actor Registration; Identity & Access Management / User Management)	**2019 June**	IVDR/MDR
Internal	Training material	MedTech Europe	Summary of EUDAMED draft documentation – part 2 (modules covered: Vigilance, Clinical Investigation / Performance Evaluation)	**2019 June**	IVDR/MDR
Internal	Training material	MedTech Europe	Summary of EUDAMED draft data exchange documentation	**2019 June**	IVDR/MDR

Internal	Training material	MedTech Europe	Device registration timelines - MedTech Europe webinar and presentation	**2019 June**	IVDR/MDR
External	Informative document	European Commission	MDR UDI and device data sets	**2019 May**	MDR
External	Informative document	European Commission	IVDR UDI and device data sets	**2019 May**	IVDR
External	Informative document	European Commission	Data exchange guidelines	**2019 May**	IVDR/MDR
External	Informative document	European Commission	Machine-to-machine (M2M) data exchange documentation for economic operators • M2M data exchange services and entity models introduction (v1 29 May 2019) • M2M data exchange services definition (v1 29 May 2019) • Service entity model XSD • Service entity model UML diagrams • XML samples	**2019 May**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-5 Registration of legacy devices in EUDAMED	**2019 April**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-4 Timelines for registration of device data elements in EUDAMED	**2019 April**	IVDR/MDR
Internal	Informative document	European Commission	EUDAMED functional specifications (v4.1)	**2019 February**	IVDR/MDR
Unique Device Identification (UDI) (TOR) and related information					
External	Position Paper	MDCG	MDCG 2020-18 Position Paper on UDI assignment for Spectacle lenses & Ready readers *(new)*	**2020 December**	MDR
Internal	Guidance	MedTech Europe	Basic UDI-DI guidance	**Revised 2020 June**	IVDR/MDR

External	Guidance	MDCG	MDCG 2018-1 v3 Guidance on Basic UDI-DI and changes to UDI-DI	**Revised 2020 March**	IVDR/MDR
External	Guidance	MDCG	Formats of AICD and HRI parts of UDI carriers **GS1** GS1 UDI HRI & AIDC formats GS1 basic UDI-DI **HIBCC** HIBCC UDI HRI & AIDC formats HIBCC basic UDI-DI **ICCBBA** ICCBBA UDI HRI & AIDC formats ICCBBA basic UDI-DI **IFA** IFA UDI HRI & AIDC formats IFA basic UDI-DI	**2019 December**	IVDR/MDR
External	Guidance	European Commission	FAQ on Unique Device Identification (UDI) System	**2019 August**	IVDR/MDR
External	Implementing Regulation	European Commission	Commission implementing decision (EU) 2019/939 of 6 June 2019 on designating issuing entities designated to operate a system for the assignment of UDIs in the field of medical devices	**2019 June**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-5 Registration of legacy devices in EUDAMED	**2019 April**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-4 Timelines for registration of device data elements in EUDAMED	**2019 April**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-2 Guidance on application of UDI rules to device-part of products referred to in Article 1(8), 1(9), 1(10) (combination products) of Regulation (EU) 2017/745 MDR	**2019 February**	MDR
External	Guidance	MDCG	MDCG 2019-1 MDCG guiding principles for issuing entities rules on Basic UDI-DI	**2019 January**	IVDR/MDR
External	Guidance	MDCG	MDCG 2018-3 Guidance on UDI for systems and procedure packs	**Revised 2020 June**	MDR
External	Guidance	MDCG	MDCG 2018-4 Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs	**2018 October**	MDR
External	Guidance	MDCG	MDCG 2018-5 UDI Assignment to Medical Device Software	**2018 October**	IVDR/MDR
External	Guidance	MDCG	MDCG 2018-6 Clarifications of UDI related responsibilities in relation to Article 16	**2018 October**	MDR

External	Guidance	MDCG	MDCG 2018-7 Provisional considerations regarding language issues associated with the UDI database	**2018 October**	IVDR/MDR
International Matters (TOR) and related information					
External	Position paper	MedTech Europe	Impact of changes under the new EU MDR to international registrations	**2020 May**	MDR
External	Position paper	MedTech Europe	Impact of changes under the new EU IVDR to international registrations	**2020 May**	IVDR
Internal	Regulatory Update	MedTech Europe	Animal By-Products: Imports & Exports from and to the United Kingdom	**2019 March**	IVDR/MDR
Internal	Guidance	MedTech Europe	How to prepare for a no deal Brexit	**2019 February**	IVDR/MDR
Internal	Guidance	MedTech Europe	Checklist - are you Brexit ready?	**2019 February**	IVDR/MDR
External	Factsheet	European Commission	Factsheet for Authorities in non-EU/EEA States on MDs and IVDs	**2018 November**	IVDR/MDR
***In vitro* diagnostic medical devices (IVD) (TOR) and related information**					
Internal	Q&A	MedTech Europe	Q&A on State of the art *(new)*	**Revised 2021 January**	IVDR
Internal	Guidance	MedTech Europe	Guidance on Annex II and III *(new)*	**2021 January**	IVDR
Internal	Q&A	MedTech Europe	Q&A on Accessories *(new)*	**2020 December**	IVDR
External	Guidance	MDCG	Classification of IVDs *(new)*	**2020 November**	IVDR
Internal	Reflection Paper	MedTech Europe	Class D devices: business or public health concern? *(new)*	**2020 October**	IVDR

Internal	Q&A	MedTech Europe	Q&A on benefit-risk assessment	**2020 August**	IVDR
External	White Paper (Q&A)	MedTech Europe (and EFPIA)	Determining the Path for Assessment of a Companion Diagnostic (CDx) under the In Vitro Diagnostic Medical Devices Regulation	**2020 June**	IVDR
Internal	eBook	MedTech Europe	Clinical Evidence Requirements for CE certification under the in vitro Diagnostic Regulation in the European Union	**2020 May**	IVDR
External	Implementing regulation	European Commission	Commission Implementing Decision on the requirements for HIV and HCV self-tests	**2020 February**	IVDR
External	Implementing regulation	European Commission	Implementing Decision with regards to Common Technical Specifications for HIV and HCV antigen and antibody combined tests	**2019 July**	IVDD
Internal	Position paper	MedTech Europe	Q&A on Surgically invasive sample-taking	**2018 November**	IVDR
Nomenclature (TOR) and related information					
External	Info sheet	European Commission	Information on EMDN	**2020 January**	IVDR/MDR
External	Info sheet	European Commission	Information on the selected CND - background and general principles	**2020 January**	IVDR/MDR
External	Guidance	MDCG	MDCG 2018-2 Future EU medical device nomenclature Description of requirements	**2018 April**	IVDR/MDR
External	Decision	MDCG	Decision on selecting the nomenclature for IVDR/MDR	**2018 March**	IVDR/MDR

Other implementation areas

External for public / Internal for MedTech Europe members	Type of doc	Source/ Owner	Document (title and link)	Date of publication	Applicable legislation
Consolidated Texts of the Regulations					
External	Regulation	EU	MDR (here) following the May and December 2019 corrigenda and the April 2020 amendment	**2020 April**	MDR
External	Regulation	EU	IVDR (here) following the May and December 2019 corrigenda	**2019 December**	IVDR
Transitional provisions					
External	Position Paper	MedTech Europe	The need for 'virtual audits' under the Medical Device and In Vitro Diagnostic Regulations in the context of a pandemic, such as COVID-19	**2020 June**	IVDR/MDR
External	Guidelines	MDCG	MDCG 2020-12 Guidance on transitional provisions for consultations of authorities on devices incorporating a substance which may be considered a medicinal product and which has action ancillary to that of the device, as well as on devices manufactured using TSE susceptible animal tissues	**2020 June**	MDR
External	Guidance	MDCG	MDCG 2020-3 Significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD	**2020 March**	MDR
External	Guidance	MDCG	MDCG 2020-2 Class I Transitional provisions under Article 120 (3 and 4) – (MDR)	**2020 March**	MDR
Internal/ External	Position paper	MedTech Europe	Significant Changes According to IVDR Article 110(3)	**2019 October**	IVDR
External	Position paper	GMED	Significant Changes According to MDR Article 120(3)	**2019 April**	MDR

Internal/ External	Joint Industry Position paper	MedTech Europe	Significant Changes According to MDR Article 120(3)	**2019 February**	MDR
External	Factsheet	European Commission	Factsheet for Authorities in non-EU/EEA States on MDs and IVDs	**2018 December**	IVDR/MDR
Internal	Training material	MedTech Europe training	MDR Transitional Provision webinar and slides	**2018 September**	IVDR/MDR
External	Explanatory documents	MedTech Europe	Explanatory documents: The transition to a new regulatory framework for IVDR and MDR	**2018 May**	IVDR/MDR
Internal	Regulatory Update	MedTech Europe	Regulatory Update on FAQ published by CAMD on IVDR/MDR transitional provisions	**2018 April**	IVDR/MDR
External	Q&A	CAMD	CAMD Transition Subgroup FAQ – MDR Transitional provisions	**2018 January**	MDR
External	Q&A	CAMD	CAMD Transition Subgroup FAQ – IVDR Transitional provisions	**2018 January**	IVDR
Scientific bodies					
External	Implementing regulation	European Commission	Implementing Decision 2019/1396 laying down the principles for designation and set up of expert panels under the In-vitro Diagnostic Medical Devices and Medical Devices Regulations	**2019 September**	IVDR/MDR
Economic operators					
Internal	Q&A	MedTech Europe	Q&A on economic operators v.3 *(new)*	**2020 November**	IVDR/MDR
Internal	Q&A	MedTech Europe	Q&A on virtual manufacturers as per EU 2017/745	**2020 January**	MDR
Internal	Reflection paper	MedTech Europe	Economic operators' responsibilities when part of the same organisation	**2019 April**	IVDR/MDR

Internal	Training material	MedTech Europe	Economic Operators webinar and slides	**2018 June**	IVDR/MDR
Labelling					
External	Position Paper	MedTech Europe	Exemptions from MDR Art. 18 *(new)*	**2020 November**	MDR
External	Campaign	MedTech Europe	Symbols for self-testing and near-patient testing (awareness campaign, zip files of symbols and translations) *(new)*	**2020 October**	IVDR
Internal	Guidance	MedTech Europe	Chemical Hazard Labelling of IVDs (CLP Regulation and Other Hazard Labelling) *(new)*	**2020 October**	IVDR
Internal/ External	Position paper	MedTech Europe	Provision of the Summary of Safety and Clinical Performance (SSCP) & link in the Instructions for Use (IFU)	**2020 March**	MDR
External	Guidance	MDCG	MDCG 2019-8 v2 Guidance on Implant cards referred to in MDR Article 18	**2020 March**	MDR
Internal	Guidance	MedTech Europe	Device type on implant card- industry interim list	**2020 February**	MDR
Internal	Guidance	MedTech Europe	Template EU Declaration of Conformity	**2020 February**	IVDR
Internal/ External	Reflection paper	MedTech Europe	MTE on extension of electronic format to all professional use IFU	**2020 February**	MDR
Internal	Guidance	MedTech Europe	Guidance on MDR language requirements	**2020 January**	MDR
Internal/ External	Guidance	MedTech Europe	Guidance on symbols for labels to comply with MDR v.2.0	**2019 December**	MDR
Internal/ External	Explanatory paper	MedTech Europe	IVDR – MDR Labelling differences: what symbols apply to IVDs	**2019 November**	IVDR
Internal	Guidance	MedTech Europe	Guidance on IVDR requirements which drive changes to labelling	**2019 October**	IVDR

Internal	Q&A	Medtech Europe	Q&A on Implant card and related material	**2019 September**	MDR
Internal	Q&A	MedTech Europe	Q&A on Labelling vol.2 (MD)	**2019 July**	MDR
Internal	Q&A	MedTech Europe	Q&A on Labelling (MD)	**2018 December**	MDR
Internal	Regulatory update	MedTech Europe	Symbols for self-testing and near-patient testing	**2018 December**	IVDR
Internal	Training material	MedTech Europe	MDR implications on labelling – webinar and presentation	**2018 October**	MDR
Environmental/chemicals/disposal					
Internal	Excel list	MedTech Europe/ COCIR	MTE-COCIR CMR 1A/1B & endocrine disrupting substances uses list *(new)*	**2021 January**	MDR
Internal	Webinar	MedTech Europe	SRD exemption under REACH (presentation and recording) *(new)*	**2020 December**	MDR/IVDR
Internal	Guidance	MedTech Europe	MDR hazardous substances requirements (v3.0) *(new)*	**2020 November**	MDR
Internal	Webinar	MedTech Europe	REACH Authorisation for DEHP in Medical Devices (presentation, factsheet and recording)	**2020 September**	MDR/IVDR
Internal	Guidance	MedTech Europe	Guidance on safe disposal of IVDs	**2019 November**	IVDR
External	Guidance	Scientific committee	SCHEER guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties	**2019 June**	MDR

Procedure Packs					
Internal	Q&A	MedTech Europe	Q&A on procedure packs and new packers' obligations: version 3.0 *(new)*	**2021 January**	MDR
External	Guidance	MDCG	MDCG 2018-3 Guidance on UDI for systems and procedure packs	**Revised 2020 June**	MDR
External	Guidance	MDCG	MDCG 2018-4 Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs	**2018 October**	MDR
Person Responsible for Regulatory Compliance (PRRC)					
External	Guidance	MDCG	MDCG 2019-7 on the Person Responsible for Regulatory Compliance (PRRC) Role referred to in IVDR/MDR Article 15	**2019 June**	IVDR/MDR
Commission factsheets					
External	Rolling plan	European Commission	MDR and IVDR implementation rolling plan *(new)*	**2020 December**	IVDR/MDR
External	Factsheet	European Commission	MDR requirements for Transparency and Public Information List of information which will be available to the public in accordance with transparency obligations / requirements once EUDAMED is fully functional	**2020 July**	MDR
External	Factsheet	European Commission	Factsheet for healthcare professionals and health institutions	**2019 June**	IVDR/MDR
External	Factsheet	European Commission	Factsheet for IVD Manufacturers	**2018 November**	IVDR
External	Factsheet	European Commission	Factsheet for MD Manufacturers	**2018 November**	MDR
External	Step by Step Guide	European Commission	Implementation Model for IVDR - Step by Step Guide	**2018 November**	IVDR

External	Step by Step Guide	European Commission	Implementation Model for MDR - Step by Step Guide	**2018 November**	MDR
External	Infographics	European Commission	Transition Timelines from the Directives to the Regulations – MDs and IVDs	**2018 November**	IVDR/MDR
External	Infographics	European Commission	Main new features of MDR and IVDR - infographics	**2018 November**	IVDR/MDR
External	Factsheet	European Commission	Factsheet for Authorised Representatives, Importers and Distributors of MDs and IVDs	**2018 November**	IVDR/MDR
External	Factsheet	European Commission	Factsheet for the Procurement Ecosystem of MDs and IVDs	**2018 November**	IVDR/MDR
External	Checklist	European Commission	Exhaustive list of requirements for manufacturers of medical devices	**2018 July**	MDR
COVID 19					
External	Proposal	European Commission	Proposal for a COUNCIL RECOMMENDATION on a common framework for the use, validation and mutual recognition of COVID-19 rapid antigen tests in the EU *(new)*	**2020 December**	
External	Database	European Commission	COVID-19 In Vitro Diagnostic Devices and Test Methods Database *(new)*	**Continuously updating**	
External	Recommendation	European Commission	COMMISSION RECOMMENDATION (EU) 2020/1743 of 18 November 2020 on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection *(new)*	**2020 November**	
External	Guidance	European Centre for Disease Prevention and Control (ECDC)	Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK *(new)*	**2020 November**	

External	Recommendation	European Commission	COMMISSION RECOMMENDATION (EU) 2020/1595 of 28 October 2020 on COVID-19 testing strategies, including the use of rapid antigen tests *(new)*	**2020 October**	External
External	Guidance	European Commission	Conformity assessment procedures for protective equipment	**Revised 2020 July**	
External	Guidance	European Commission	How to verify that medical devices and personal protective equipment can be lawfully placed on the EU market and thus purchased and used – also in the COVID-19 context	**2020 May**	IVDD/ AIMDD/ MDD
External	Guidance	European Commission	Guidance on regulatory requirements for medical face masks	**2020 June**	MDD
External	Database	European Commission	The COVID-19 In Vitro Diagnostic Devices and Test Methods Database	**2020 June**	IVDD
External	Guidance	MDCG	MDCG 2020-9 Regulatory requirements for ventilators and related accessories	**2020 April**	MDR
External	Guidance	MDCG	MDCG 2020-4 Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions	**2020 April**	IVDD/ AIMDD/ MDD
External	Guidance	European Commission	Current performance of COVID-19 test methods and devices and proposed performance criteria - Working document of Commission services	**2020 April**	IVDD/ AIMDD/ MDD
External	Guidance	European Commission	Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context	**2020 April**	IVDD/ AIMDD/ MDD
External	Guidance	European Commission	Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19	**2020 April**	
External	Guidance	European Commission	Guidelines on COVID-19 in vitro diagnostic tests and their performance	**2020 April**	IVDD

External	Guidance	IMDRF	IMDRF Standards Checklist modified in scope of COVID-19	**2020 April**	
External	Communication	European Commission	Short-term EU health preparedness for COVID-19 outbreaks	**2020 July**	
Other					
External	Information Notice	European Commission	Commission Notice on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment *(new)*	**2021 January**	IVDR/MDR
External	Implementing Regulation	European Commission	Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use device	**2020 August**	MDR
Internal	Guidance	MedTech Europe	Check list for Contractual Arrangement between Medical Device Manufacturer and Notified Body concerning Surveillance Duties for Legacy Devices during the Grace Period of the Medical Devices Regulation	**2020 June**	IVDR/MDR
External	Guidance	MDCG	MDCG 2019-3 (v2) Interpretation of Article 54(2)b	**Revised 2020 April**	MDR
Internal	Guidance	MedTech Europe	Guidance on Annex I, IVD Regulation 2017/746/EU	**2019 December**	IVDR
External	Q&A	European Medicines Agency	Questions & Answers on Implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations ((EU) 2017/745 and (EU) 2017/746)	**Revised 2019 October**	MDR
External	Implementing regulation	European Commission	Implementing Decision 2019/1396 laying down the principles for designation and set up of expert panels under the In-vitro Diagnostic Medical Devices and Medical Devices Regulations	**2019 September**	IVDR/MDR

External	Discussion paper	MedTech Europe	Device-drug combination products: Shall the 210-day pharma authority consultation be repeated for legacy products?	**2019 May**	MDR
Internal	Q&A	MedTech Europe	Q&A on the interplay between the EU General Data Protection Regulation and the IVDR/MDR	**2019 May**	IVDR/MDR
Internal	Q&A	MedTech Europe	MTE internal Q&A series to support MD Regulation implementation (implant cards, hazardous substances)	**2018 December**	MDR
Internal	Q&A	MedTech Europe	Q&A on documentation which may be required to be provided by the manufacturer under the MDR	**2018 October**	MDR
Internal	Training material	MedTech Europe	IVDR/MDR implications for Quality Management Systems webinar and slides	**2018 April**	IVDR/MDR
Internal	Q&A	MedTech Europe	Q&A 69 on documentation which may be required to be provided by the manufacturer under the IVDR	**2018 March**	IVDR
Internal	Q&A	MedTech Europe	General Data Protection Regulation (EU) 2016/679	**2018 March**	IVDR/MDR
Internal	Q&A	MedTech Europe	Consent under the General Data Protection Regulation	**2018 March**	IVDR/MDR
Internal	Q&A	MedTech Europe	MTE internal Q&A series to support IVD Regulation implementation (Single Declaration of Conformity, Performance studies. Use of legacy data/studies to demonstrate clinical evidence)	**2018 February**	IVDR
External	Training material	MedTech Europe	IVDR Flowchart	**2017 December**	IVDR
External	Training material	MedTech Europe	MDR Flowchart	**2017 December**	MDR

Part II: Rolling Plan – Documents in the pipeline

MDCG Working Groups					
External for public / Internal for MedTech Europe members	**Type of document**	**Source/ Owner**	**Document (title and link)**	**Estimated time for accomplishment (ETA)**	**Applicable legislation**
Notified Bodies Oversight (NBO) (TOR) and related information (*Closed* – covers requirements set out by designating authorities specifically for Notified Bodies)					
External	Guidance	NBO	Q&A on notified bodies – new questions to be added to the document already published	ETA 2021	IVDR/MDR
External	Guidance	NBO	Batch verification on class D IVDs	ETA 2021	IVDR
External	Guidance	NBO	Explanatory note on IVDR codes	ETA 2021	IVDR
External	Guidance	NBO	Applicability of clinical evaluation consultation procedure	ETA 2021	MDR
Standards (TOR) and related information					
External	Guidance	MDCG	Specific aspects of medical devices standardisation	TBD	IVDR/MDR
External	Technical Specification	ISO	Quality Practice for detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods *(newly added)*	ETA 2021 Q4	
External	Implementing Decision	European Commission	MDR/IVDR Standardisation Request *(newly added)*	ETA 2021 Q1	IVDR/MDR
Clinical Investigation and Evaluation (CIE) (TOR) and related information					

External	Form	MDCG	Serious Adverse Event (SAE) report	ETA 2021	MDR
External	Template	MDCG	Clinical Investigation Assessment	ETA 2021	MDR
External	Template	MDCG	Clinical Investigation application	ETA 2021	MDR
External	Q&A	MDCG	Q&A on Clinical Investigation	ETA 2021 Q2	MDR
External	Processes and templates	MDCG	CI and PS Assessments – Input to EUDAMED CIE	ETA 2021	MDR
Post-Market Surveillance and Vigilance (PMSV) (TOR) and related information					
External	Guidance	MDCG	Post-Market Surveillance guidance	Task Force to be set up	IVDR/MDR
External	Forms	MDCG	Harmonised reporting forms	Several Task Forces on-going Periodic Safety Report (PSR), the Periodic Safety Update Report (PSUR) and the Trend report ETA 2021	IVDR/MDR
External	Guidance	MDCG	Periodic Safety Update Report (PSUR) Guidance for Medical Device Manufacturers	ETA Q2 2021	MDR
External	Guidance	MDCG	MDR Vigilance requirements	ETA 2021	MDR
Market Surveillance (TOR) and related information *(Closed – for competent authorities only)*					
External	Guidance	MDCG	Authorised Representatives	ETA 2021	IVDR/MDR

External	Guidance	MDCG	Re-labelling & Re-packaging	ETA 2021	IVDR/MDR
External	Q&A	MDCG	Custom-Made & Adaptable Devices	ETA 2021	MDR
External	Guidance	MDCG	In-house manufacturers	ETA 2021	IVDR/MDR
External	Guidance	MDCG	Update of PRRC Guidance *(new)*	ETA 2021	IVDR/MDR
External	Q&A	MDCG	Importers & Distributors *(new)*	ETA 2021	IVDR/MDR
Borderline and Classification (B&C) (TOR) and related information					
External	Guidance	MDCG	Borderline with medicinal products (including general guidance, definitions of pharmacological, immunological and metabolic means of action and diagnosis, and consultation procedures of medicines authorities)	ETA 2021 Q2	IVDR/MDR
External	Guidance	MDCG	Classification of medical devices	ETA 2021 Q2	MDR
New Technologies (TOR) and related information					
External	Guidance (?)	MDCG	Qualification of smart device hardware supporting MDSW *(newly added)*	TBD	IVDR/MDR
External	Guidance	MDCG	Legal status of app providers	ETA 2021	IVDR/MDR
External		MDCG	Artificial Intelligence under MDR/IVDR framework	TBD (preliminary discussions)	IVDR/MDR
EUDAMED (TOR) and related information					

External	Guidance	MDCG	Linking several Basic UDI-DIs to the Summary of safety and clinical performance (SSCP) and product certificate registered in EUDAMED	ETA 2021	MDR
External	Guidance	MDCG	Harmonised administrative practices and alternative technical solutions in the absence of EUDAMED	ETA 2021	IVDR/MDR
External	Platforms for device and certificate registration	European Commission	Release EUDAMED modules for the registration of devices (including UDI) and certificates	ETA 2021 Q2	IVDR/MDR
External	Implementing regulation	European Commission	Implementing regulation on support, change management and maintenance rules of EUDAMED	ETA 2021 Q1	IVDR/MDR
External	Guidance	European Commission	Management of Legacy device in EUDAMED	TBC	IVDR/MDR
Unique Device Identification (UDI) (TOR) and related information					
External	Guidance	MDCG	Integration of UDI in manufacturer's QMS	In drafting phase ETA 2021	IVDR/MDR
External	Guidance	MDCG	Guidance on UDI rules for specific device types (e.g., contact lenses) [+ other devices with high number of UDI-DIs] *(second part newly added)*	In drafting phase ETA 2021	IVDR/MDR
External	Guidance	MDCG	Endorsement of Annexes to IMDRF N48 'UDI System Application Guide' (package configurations, direct marking, IVD kits, software)	In drafting phase ETA 2021	IVDR/MDR
External	Guidance	MDCG	Illustrative examples for assignment of Basic UDI-DI and UDI-DI	In drafting phase ETA 2021	IVDR/MDR
External	Guidance	MDCG	List of values for certain data fields (clinical size + warnings and contraindications)	ETA 2021	IVDR/MDR
***In vitro* diagnostic medical devices (IVD) (TOR) and related information**					

Internal	eBook	MedTech Europe	Clinical Evidence Requirements for CE certification under the in vitro Diagnostic Regulation in the European Union Version *2*	Approval phase ETA 2021 Q1-Q2	IVDR
Internal	Q&A	MedTech Europe	Q&A Near Patient Testing	In drafting phase - TBD	IVDR
Internal	Q&A	MedTech Europe	Q&A Clinical Data Outside EU	In drafting phase - TBD	IVDR
Internal	Regulatory Update	MedTech Europe	Update on CE marking under the IVD Regulation (EU) 2017/746	In drafting phase – ETA 2021 Q1	IVDR
Internal	Document	MedTech Europe	Performance specifications for COVID-19 tests: NAAT, antigen, antibody *(newly added)*	In consultation phase – ETA 2021 Q1	IVDR
External	Guidance	MDCG	Performance evaluation	In consultation phase – ETA 2021 Q1	IVDR
External	Guidance	MDCG	Frequency of batch verification *(newly added)*	ETA 2021 Q1	IVDR
External	Implementing regulation	European Commission	Implementing regulation on Common Specifications (transfer of existing IVD Directive Common Technical Specifications into IVDR Common Specifications)	ETA 2021 Q2	IVDR
External	Guidance	MDCG	Guidance on state of the art for COVID-19 antibody tests	In consultation phase – ETA 2021	IVDR
External	Implementing regulation	European Commission	Implementing regulation on Common Specifications COVID-19 *(newly added)*	First draft will soon be sent for consultation – ETA 2021	IVDR
External	Implementing regulation	European Commission	Implementing regulation on Common Specifications Kidd and Duffy	ETA 2021	IVDR

External	Implementing regulation	European Commission	Implementing regulation on Common Specifications Chagas and Syphilis	ETA 2021	IVDR
External	Implementing regulation	European Commission	Implementing regulation on Common Specifications Cytomegalovirus and Epstein-Barr Virus	ETA 2021	IVDR
External	Implementing regulation	European Commission	Implementing regulation on Common Specifications Hepatitis E	ETA 2022-23	IVDR
External	Implementing regulation	European Commission	Implementing regulation on Common Specifications Plasmodium and Toxoplasma *(newly added)*	ETA 2022-23	IVDR
External	Implementing regulation	European Commission	Implementing regulation on Common Specifications Highly virulent pandemic influenza virus *(newly added)*	ETA 2022-23	IVDR
External	Implementing regulation	European Commission	Implementing regulation on Common Specifications SARS & MERS *(newly added)*	ETA 2022-23	IVDR
External	Implementing regulation	European Commission	Implementing regulation on Common Specifications Ebola virus, Lassa virus, Crimean-Congo hemorrhagic fever (CCHF) virus and Marburg virus *(newly added)*	ETA 2022-23	IVDR
External	Guidance	MDCG	Consensus document/Guidance on performance evaluation of Companion Diagnostics	ETA 2022?	IVDR
External	Guidance/ template	MDCG	SSP template and guidance	ETA 2021 Q2?	IVDR
External	Guidance	MDCG	Qualification of assays used in clinical trials of medicinal products	ETA 2021 Q1?	IVDR
External	Guidance	MDCG	Conditions for in-house devices *(newly added)*	TBD	IVDR
Internal	Q&A	MedTech Europe	Substantial changes *(newly added)*	ETA 2021 Q1-Q2	IVDR
Internal	Q&A	MedTech Europe	In-house assays *(newly added)*	ETA 2021 Q1-Q2?	IVDR

External	Implementing decision	MDCG	Implementing act for the appointment of EU Reference Laboratories - EURL	ETA 2021	IVDR
Nomenclature (TOR) and related information					
External	Guidance	MDCG	Rules and process for update of EMDN	ETA 2021	IVDR/MDR
External	List	MDCG	1st release of EMDN	ETA 2021	IVDR/MDR
External	Guidance	MDCG	Rules for allocation of EMDN to UDI-DI	ETA 2021 Q1	IVDR/MDR
External	Guidance	MDCG	Procedures for the annual and ad-hoc updates of EMDN	ETA 2021 Q1	
External	Mapping	European Commission	Mapping EMDN-GMDN package	N/A	
External	List	MDCG	Translation of EMDN	ETA – TBD	IVDR/MDR
External	List	MDCG	EMDN terms to be used for implant card purposes	ETA 2021	IVDR/MDR

Other implementation areas

External for public / Internal for MedTech Europe members	Type of doc	Source/ Owner	Document (title and link)	Estimated time for accomplishment (ETA)	Applicable legislation
Transitional provisions					
External	Guidance	MDCG	Significant changes IVDR	ETA 2021	IVDR

Labelling					
Internal	Guidance	MedTech Europe	Guidance on IVDR language requirements	ETA 2021	IVDR
Environmental/chemicals/disposal					
Internal	Guidance	MedTech Europe	MTE guidance on Hazardous Substances Requirements under the IVDR *(newly added)*	ETA 2021 Q1-Q2	IVDR
Person Responsible for Regulatory Compliance (PRRC)					
External	Guidance	MDCG	Update of Person Responsible for Regulatory Compliance (PRRC) document	TF has been set up ETA 2021	IVDR/MDR
Electronic Instructions for Use					
External	Implementing Regulation	European Commission	Implementing act on Electronic Instructions for Use (to replace Regulation (EU) 207/2012)	ETA 2021 (Q1 for the draft act)	MDR
Annex XVI devices without medical purpose					
External	Implementing Regulation	European Commission	Common specifications for Annex XVI devices without medical purpose	ETA 2021 Q2	MDR
Parts & Components					
Internal	Reflection paper/Q&A	MedTech Europe	Questions & Answers/ Reflection Paper addressing parts and components (MDR. Art. 23)	ETA 2021 Q1- Q2	MDR