MedTech Europe
from diagnosis to cure

**Tracking tool – available documents supporting IVDR/MDR implementation**

**Version: 19 November 2019**

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 **– 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**

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.).

**Note: Only MedTech Europe members have access to internal documents. If your organisation is a member, please ask for a login.**

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.

This tracking tool will be updated periodically – please search for the indication ***(new)*** in order to see which sources were added most recently. 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.

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## MDCG Working Groups

| External for public / Internal for MedTech Europe members | Type of document | Source/ Owner | Document (title and link) | Date of publication or estimated time for accomplishment (ETA)<br>• *Publication date*<br>• *In drafting phase – ETA*<br>• *Waiting for draft – ETA* | Applicable legislation |
|---|---|---|---|---|---|
| **Notified Bodies Oversight (NBO) (TOR) and related information**<br>(*Closed* – covers requirements set out by designating authorities specifically for Notified Bodies) | | | | | |
| External | Guidance | NBOG | NBOG BPG 2017-1<br>Best practice guidance on designation and notification of conformity assessment bodies | **2018 February (rev.3)** | IVDR/MDR |
| External | Guidance | NBOG | NBOG BPG 2017-2<br>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<br>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 | Template | NBOG | NBOG F 2017-2<br>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 F 2017-3<br>Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR) | **2018 May (rev.2)** | MDR |
| External | Guidance | NBOG | NBOG F 2017-4<br>Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR) | **2018 May (rev.2)** | IVDR |
| External | Template | NBOG | NBOG F 2017-5<br>Preliminary assessment review template (MDR) | **2018 May (rev.1)** | MDR |

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| External | Template | NBOG | NBOG F 2017-6<br>Preliminary assessment review template (IVDR) | **2018 May (rev.1)** | IVDR |
| External | Guidance | NBOG | NBOG F 2017-7<br>Review of qualification for the authorisation of personnel (MDR) | **2018 May (rev.1)** | MDR |
| External | Guidance | NBOG | NBOG F 2017-8<br>Review of qualification for the authorisation of personnel (IVDR) | **2018 May (rev.1)** | IVDR |
| 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 | State-of-play of joint assessments of Notified Bodies in the medical device sector, DG GROW.DDG.D4 | **2019 October** | 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 |
| External | Guidance | MDCG | MDCG 2019-6 Questions and answers: Requirements relating to notified bodies | **2019 June** | IVDR/MDR |
| External | Guidance | MDCG | MDCG 2019-6 v2: Updated version of Questions and answers: Requirements relating to notified bodies ***(new)*** | **2019 October** | IVDR/MDR |

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| External | Guidance | MDCG | MDCG 2019-12: Designating Authority's Final Assessment Form Under MDR, IVDR ***(new)*** | **2019 October** | IVDR/MDR |
| External | Guidance | NBO | Sampling of devices under EU QMS conformity assessment ***(new)*** | Estimated by end-2019 | IVDR/MDR |
| External | Guidance | NBO | Significant changes ***(new)*** | TBD – TF to be set up | IVDR/MDR |
| External | Guidance | NBO | Q&A on Notified bodies – new questions to be added to the document already published ***(new)*** | Estimated 2020 | IVDR/MDR |
| External | Guidance | NBO | Explanatory note on codes ***(new)*** | Estimated by end-2019 | IVDR/MDR |
| External | Guidance | NBO | Batch verification on class D IVDs ***(new)*** | TBD | IVDR/MDR |
| External | Guidance | NBO | Applicability of clinical evaluation consultation procedure ***(new)*** | TBD | MDR |
| **2. Standards (TOR) and related information** | | | | | |
| External | Implementing Act | European Commission | Standardisation request - MedTech Europe response to the draft Standardisation request ***(new)*** | Endorsement expected 2019 | IVDR/MDR |
| External | Position Paper | MedTech Europe | MedTech Europe position on the proposed draft Standardisation Request for IVDR and MDR | **2019 May** | IVDR/MDR |
| Internal | Guidance/Position paper | MedTech Europe | Industry's approach in the absence of the harmonised standards | ETA 2019 Q4 | IVDR/MDR |
| **3. Clinical Investigation and Evaluation (CIE) (TOR) and related information** | | | | | |
| External | Guidance | MDCG | MDCG 2019-9 Summary of Safety and Clinical Performance - SSCP ***(new)*** | **2019 September** | MDR |
| External | Guidance | MDCG | Equivalence ***(new)*** | Currently under extended consultation within the Work Package | MDR |

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| External | Guidance | MDCG | Clinical evidence needed for medical devices previously certified under Directives 93/42/EC and 90/385/EC (legacy medical devices) ***(new)*** (this should include ''sufficient clinical data'') | Currently under extended consultation within the Work Package | MDR |
| External | Template | MDCG | Clinical Evaluation Assessment Report (CEAR) ***(new)*** | Under consultation within the work package | MDR |
| External | Form | MDCG | Serious Adverse Event (SAE) reporting Eudamed requirements - Input to Eudamed CIE ***(new)*** | Endorsement expected 2019 | MDR |
| External | Form | MDCG | Serious Adverse Event (SAE) report - Input to EUDAMED CIE ***(new)*** | Endorsement expected 2019 | MDR |
| External | Template | MDCG | Post-Market Clinical Follow-Up Plan (PMCF) ***(new)*** | Endorsement expected 2019 | MDR |
| External | Template | MDCG | Post-Market Clinical Follow-Up Plan (PMCF) Update ***(new)*** | Endorsement expected 2019 | MDR |
| External | Template | MDCG | Clinical Investigation Assessment – Input to EUDAMED CIE ***(new)*** | Endorsement expected 2019 | MDR |
| External | Template | MDCG | Clinical Investigation application – Input to Eudamed CIE | Endorsement expected 2019 | MDR |
| External | Processes and templates | MDCG | CI and PS Assessments – Input to Eudamed CIE | Endorsement expected 2019 | MDR |
| External | Process flow | MDCG | SAE reporting - Input to EUDAMED CIE | Endorsement expected 2019 | 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 |
| **4. Post-Market Surveillance and Vigilance (PMSV) (TOR) and related information** | | | | | |
| External | Guidance | MDCG | Post-Market Surveillance requirements | TF to be set up | IVDR/MDR |

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| Internal /external | Guidance | MedTech Europe | Vigilance guidance (industry proposal to feed into MDCG guidance) ***(new)*** | **2019 September** | IVDR/MDR |
| External | Guidance | MDCG | Vigilance requirements | TF has been set up | IVDR/MDR |
| External | Guidance | MDCG | Meddev 2.12.1 rev8 Clarification document ***(new)*** ('Additional Guidance Regarding the Vig. (…) | **2019 July** | IVDR/MDR |
| External | Forms | MDCG | Harmonised reporting forms for incidents | Several Task Forces on-going | IVDR/MDR |
| External | Template | MDCG | Manufacturer Incident Reporting (MIR) template version 7.2 ***(new)*** | **Updated: 2019 September**<br>**2019 January** | IVDR/MDR |
| External | Guidance | MDCG | Helptext MIR document v.7.2 ***(new)*** | **Updated: 2019 September**<br>**2018 December** | IVDR/MDR |
| External | Q&A | MDCG | Manufacturer Incident Report Q&A | ETA 2019 Q4 | IVDR/MDR |
| External | Template | MDCG | New manufacturer incident report XSD files (for implementation in manufacturer' databases) ***(new)*** | **Updated: 2019 September**<br>**2018 December** | IVDR/MDR |
| External | Template | MDCG | Manufacturer incident report for importing XML file with Adobe Professional 2020 ***(new)*** | **2019 September** | IVDR/MDR |
| External | Guidance | MDCG | MIR Changelog file 2020 ***(new)*** | **2019 September** | 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 |

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| External | Template | MDCG | Questions and Answers to fill in the Field Safety Notice (FSN) | **2018 October** | IVDR/MDR |
| External | Guidance | MDCG | Guidance for Medical Device Manufacturers on Completion of Periodic Safety Update Reports | In drafting phase – ETA? | IVDR/MDR |
| External | Template | MDCG | Periodic Safety Update Report Eudamed template | In drafting phase – ETA? | 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 | Overview of Post Market Surveillance in the EU - webinar and presentation | **2018 September** | 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 |
| External | Guidance | MDCG | DSVG 03 - Cardiac Implantable Electronic Devices (CIED) vigilance reporting guidance ***(new)*** | **2019 September** | MDR |
| External | Guidance | MDCG | DSVG 04 - Breast Implants vigilance reporting guidance ***(new)*** | **2019 September** | MDR |
| **5. Market Surveillance (TOR) and related information** *(Closed – for competent authorities only)* | | | | | |
| External | Guidance | MDCG | Class I manufacturers ***(new)*** | Endorsement expected 2019 | MDR |

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| External | Guidance | MDCG | Update of PRRC document ***(new)*** | TF has been set up<br>ETA 2020 | IVDR/MDR |
| External | Guidance | MDCG | Authorised Representatives ***(new)*** | TF to be set up<br>ETA 2020 | IVDR/MDR |
| External | Guidance | MDCG | In-house manufacturers ***(new)*** | TBD | IVDR/MDR |
| External | | | Joint Action on Market Surveillance of Medical Devices (JAMS) | | |
| **6. Borderline and Classification (B&C) (TOR) and related information** | | | | | |
| External | Guidance | MDCG | Manual on Borderline and Classification, Version 1.22 | **2019 May** | IVDR/MDR |
| External | Guidance | MDCG | Revision of MEDDEV 2.1/3 rev.3 guidance on Borderline products (including current MEDDEV 2.1.1. on definitions) | Waiting for draft<br>ETA 2019 Q4 | IVDR/MDR |
| External | Guidance | MDCG | Revision of MEDDEV 2.4/1 rev.9 guidance on Classification | Waiting for draft<br>ETA 2019 Q4 | MDR |
| 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) ***(new)*** | TBD | MDR |
| External | Guidance | MDCG | Classification of medical devices ***(new)*** | TBD | MDR |
| **7. New Technologies MDCG working group (TOR) and related information** | | | | | |
| External | Guidance | MDCG | Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR | **2019 October** | IVDR/MDR |
| External | Guidance | MDCG | Clinical Evaluation of Software ***(new)*** | In drafting phase<br>ETA 2019 Q4 | IVDR/MDR |

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| External | Implementing act | European Commission | Implementing act for electronic Instructions for use (to replace EU regulation 207/2012) | In drafting phase - 1st comments submitted ETA 2020 Q2 | IVDR/MDR |
| External | Guidance | MDCG | Cybersecurity of Software ***(new)*** | In drafting phase ETA 2019 Q4 | IVDR/MDR |
| Internal | Guidance | MedTech Europe | Software Labelling Best Practice Guide | In drafting phase ETA 2019 Q4 | IVDR/MDR |
| **8. Eudamed Commission working groups** (not transferred under MDCG) | | | | | |
| External | Implementing regulation | European Commission | Implementing regulation on support, change management and maintenance rules of Eudamed | Waiting for draft ETA 2019 Q4 | IVDR/MDR |
| Internal | Informative document | European Commission | Eudamed functional specifications (v4.1) | **2019 February** | 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) ***(updated)*** | **2019 June** | IVDR/MDR |
| Internal | Training material | MedTech Europe | Summary of Eudamed draft documentation – part 2 (modules covered: Vigilance, Clinical Investigation / Performance Evaluation) ***(updated)*** | **2019 June** | IVDR/MDR |
| Internal | Training material | MedTech Europe | Summary of Eudamed draft data exchange documentation ***(updated)*** | **2019 June** | IVDR/MDR |
| External | Guidance | MDCG | 2019-4 Timelines for registration of device data elements in EUDAMED | **2019 April** | IVDR/MDR |
| External | Guidance | MDCG | 2019-5 Registration of legacy devices in EUDAMED | **2019 April** | IVDR/MDR |
| External | Guidance | European Commission | Management of Legacy device in Eudamed | TBC | IVDR/MDR |
| Internal | Training material | MedTech Europe | Device registration timelines - MedTech Europe webinar and presentation ***(new)*** | **2019 June** | IVDR/MDR |

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| 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 | EUDAMED UDI device data dictionary V3.0 | **2019 May** | IVDR/MDR |
| 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<br>• M2M data exchange services and entity models introduction (v1 29 May 2019)<br>• M2M data exchange services definition (v1 29 May 2019)<br>• Service entity model XSD<br>• Service entity model UML diagrams<br>• XML samples | **2019 May** | IVDR/MDR |
| **9. Unique Device Identification (UDI) (TOR) and related information** | | | | | |
| External | Guidance | MDCG | 2019-5 Registration of legacy devices in EUDAMED | **2019 April** | IVDR/MDR |
| External | Guidance | MDCG | Guidance on Basic UDI-DI and changes to UDI-DI (MDCG 2018-1 v2) | **Revised 2019 March 2018 April** | IVDR/MDR |
| External | Guidance | MDCG | Guidance on UDI for systems and procedure packs (MDCG 2018-3) | **2018 October** | MDR |
| External | Guidance | MDCG | Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs (MDCG 2018-4) | **2018 October** | MDR |
| External | Guidance | MDCG | UDI Assignment to Medical Device Software (MDCG 2018-5) | **2018 October** | IVDR/MDR |
| External | Guidance | MDCG | Clarifications of UDI related responsibilities in relation to Article 16 (MDCG 2018-6) | **2018 October** | MDR |

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| External | Guidance | MDCG | Provisional considerations regarding language issues associated with the UDI database (MDCG 2018-7) | **2018 October** | IVDR/MDR |
| External | Guidance | European Commission | FAQ on Unique Device Identification (UDI) System ***(new)*** | **2019 August** | 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 | Integration of UDI in manufacturer's QMS ***(new)*** | In drafting phase<br>ETA 2019 Q4 | IVDR/MDR |
| External | Guidance | MDCG | Guidance on UDI rules for specific device types ***(new)*** | In drafting phase<br>ETA 2019 Q4 | IVDR/MDR |
| External | Guidance | MDCG | Formats of AICD and HRI parts of UDI carriers ***(new)*** | **2019 October** | IVDR/MDR |
| External | Guidance | MDCG | Guidance on UDI carrier and UDI marking based on IMDRF work (package configurations, direct marking, IVD kits, software) ***(new)*** | In drafting phase<br>ETA 2020 Q1 | IVDR/MDR |
| External | Guidance | MDCG | Illustrative examples for assignment of Basic UDI-DI and UDI-DI | In drafting phase<br>ETA 2019 Q4 | 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 |
| **10. International Matters (TOR) and related information** | | | | | |
| External | | MDCG | Taking into account MDSAP for NB | TBD | IVDR/MDR |
| External | Factsheet | European Commission | Factsheet for Authorities in non-EU/EEA States on MDs and IVDs | **2018 November** | IVDR/MDR |
| Internal | Guidance | MedTech Europe | How to prepare for a no deal Brexit | **2019 February** | IVDR/MDR |

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| Internal | Guidance | MedTech Europe | Checklist - are you Brexit ready? | **2019 February** | IVDR/MDR |
| Internal | Regulatory Update | MedTech Europe | Animal By-Products: Imports & Exports from and to the United Kingdom | **2019 March** | IVDR/MDR |
| **11. *In vitro* diagnostic medical devices (IVD) (TOR) and related information** | | | | | |
| External | Guidance | MDCG | Performance evaluation ***(new)*** | In drafting phase<br>ETA ? | IVDR |
| External | Guidance | MDCG | Consensus document/Guidance on performance evaluation of Companion Diagnostics | In drafting phase<br>ETA ? | IVDR |
| External | Guidance | MDCG | Classification of IVDs ***(new)*** | In drafting phase<br>ETA 2019 Q4 | IVDR |
| External | Implementing regulation | European Commission | Implementing regulation on Common Specifications (convert of existing IVD Directive Common Technical Specifications into IVDR Common Specifications) ***(new)*** | Waiting for draft<br>ETA 2019 Q4 | IVDR |
| External | Implementing regulation | European Commission | Implementing Decision with regards to Common Technical Specifications for HIV and HCV antigen and antibody combined tests ***(new)*** | **2019 July** | IVDD |
| External | Guidance | MDCG | SSP template and guidance ***(new)*** | ETA – TBD | IVDR |
| External | Guidance | MDCG | Qualification of assays used in clinical trials of medicinal products ***(new)*** | ETA – TBD | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on benefit-risk assessment | In drafting phase<br>ETA 2019 Q4 | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on clinical evidence of Companion Diagnostics | In drafting phase<br>ETA 2019 Q4 | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on Post-Market Performance Follow-up | In drafting phase<br>ETA 2019 Q4 | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on Summary of Safety and Performance | **2019 January** | IVDR |

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| Internal | Q&A | MedTech Europe | Q&A on Scientific validity vs clinical utility_Version 2 | **2019 June** | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on Clinical benefit of IVD | **2019 June** | IVDR |
| Internal | Q&A | MedTech Europe | Q&A Examples of intended purposes | **2018 November** | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on Performance Evaluation documentation | **2018 November** | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on Published experience | **2018 November** | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on State of the art | **2018 November** | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on Surgically invasive sample-taking | **2018 November** | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on Intended purpose | **2018 November** | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on Similar vs Equivalent | **2018 November** | IVDR |
| Internal | Q&A | MedTech Europe | Q&A on Clinical Evidence Levels | **2018 November** | IVDR |
| **12. Nomenclature (TOR) and related information** | | | | | |
| External | ? | MDCG | Information package on EMDN (for website) ***(new)*** | ETA –2019 Q4 | IVDR/MDR |
| External | Guidance | MDCG | Rules and process for update of EMDN ***(new)*** | ETA - 2019 | IVDR/MDR |
| External | List | MDCG | 1st release of EMDN ***(new)*** | ETA – TBD | IVDR/MDR |

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| External | Guidance (?) | MDCG | Mapping CND-GMDN package***(new)*** | ETA –2019 Q2 | IVDR/MDR |
| External | List (?) | MDCG | Translation of EMDN ***(new)*** | ETA – TBD | IVDR/MDR |
| External | List | MDCG | EMDN terms to be used for implant card purposes***(new)*** | ETA – 2019 | 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 |
| **13. Annex XVI -** *Closed – for competent authorities only* | | | | | |
| External | Guidance | MDCG | Qualification of devices listed in Annex XVI | TBD | MDR |

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## Other implementation areas

| External for public / Internal for MedTech Europe members | Type of doc | Source/Owner | Document (title and link) | Date of publication or estimated time for accomplishment (ETA)<br>*- Publication date*<br>*- In drafting phase – ETA*<br>*- Waiting for draft – ETA* | Applicable legislation |
|---|---|---|---|---|---|
| **Consolidated Texts of the Regulations** | | | | | |
| External | Regulation | EU | IVDR (here)- and MDR (here) following the May 2019 corrigenda ***(new)*** | **2019 August** | IVDR/MDR |
| **Transitional provisions** | | | | | |
| External | Q&A | CAMD | CAMD Transition Sub Group FAQ – MDR Transitional provisions | **2018 January** | MDR |
| External | Q&A | CAMD | CAMD Transition Sub Group FAQ – IVDR Transitional provisions | **2018 January** | IVDR |
| External | Factsheet | European Commission | Factsheet for Authorities in non-EU/EEA States on MDs and IVDs | **2018 December** | 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 |
| Internal | Training material | MedTech Europe training | MDR Transitional Provision webinar and slides | **2018 September** | IVDR/MDR |
| External | Joint Industry Position paper | MedTech Europe | Significant Changes According to MDR Article 120(3) | **2019 February** | MDR |
| External | Position paper | GMED | Significant Changes According to MDR Article 120(3) | **2019 April** | MDR |
| External | Position paper | MedTech Europe | Significant Changes According to IVDR Article 110(3) | **2019 October** | IVDR |

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| **Economic operators** | | | | | |
| Internal | Training material | MedTech Europe | Economic Operators webinar and slides | **2018 June** | IVDR/MDR |
| Internal | Q&A | MedTech Europe | Q&A on economic operators ***(new)*** | **2019 September** | IVDR/MDR |
| Internal | Reflection paper | MedTech Europe | Economic operators' responsibilities when part of the same organisation | **2019 April** | IVDR/MDR |
| Internal | Q&A | MedTech Europe | Q&A on virtual manufacturers as per EU 2017/745 | ETA 2019 Q4 | MDR |
| External | Position paper | MedTech Europe | MTE industry paper on virtual manufacturers as per EU 2017/745 | ETA 2019 Q4/ 2020 Q1 | MDR |
| **Labelling** | | | | | |
| Internal | Training material | MedTech Europe | MDR implications on labelling – webinar and presentation | **2018 October** | MDR |
| External | Guidance | MDCG | MDCG 2019-8 Guidance on Implant cards referred to in MDR Article 18 ***(new)*** | **2019 June** | MDR |
| Internal | Q&A | Medtech Europe | Q&A on Implant card and related material ***(new)*** | **2019 September** | MDR |
| Internal | Q&A | MedTech Europe | Q&A on Labelling (MD) | **2018 December** | MDR |
| Internal | Q&A | MedTech Europe | Q&A on Labelling vol.2 (MD) ***(new)*** | **2019 July** | MDR |
| Internal/external | Guidance | MedTech Europe | Guidance on symbols for labels to comply with MDR | **2019 May** | MDR |
| Internal | Regulatory update | MedTech Europe | Symbols for self-testing and near-patient testing | **2018 December** | IVDR |
| Internal | Guidance | MedTech Europe | Guidance on IVDR requirements which drive changes to labelling ***(new)*** | **2019 October** | IVDR |
| Internal | Guidance | MedTech Europe | Guidance on MDR language requirements | ETA 2020 | MDR |
| Internal | Guidance | MedTech Europe | Guidance on IVDR language requirements | ETA 2020 | IVDR |
| Internal | Guidance | MedTech Europe | Guidance on labelling of software | ETA 2020 Q1-Q2 | IVDR/MDR |
| Internal | Guidance | MedTech Europe | Template EU Declaration of Conformity | ETA Q4 2019 | IVDR |
| **Environmental/chemicals/disposal** | | | | | |

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| 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 ***(new)*** | **2019 September** | MDR |
| Internal | Guidance | MedTech Europe | MDR hazardous substances requirements (v2.0) | **2019 July** | MDR |
| Internal | Excel list | MedTech Europe/ COCIR | MTE-COCIR CMR 1A/1B & endocrine disrupting substances uses list ***(new)*** | **2019 September** | MDR |
| Internal | Guidance | MedTech Europe | Guidance on safe disposal of IVDs | ETA 2019 Q4 | IVDR |
| Internal | Guidance | MedTech Europe | Guidance on the CLP Regulation | ETA 2019 Q4 | IVDR |
| **Scientific bodies** | | | | | |
| External | Implementing regulation | European Commission | Implementing regulation on setting up EU Reference Laboratories | Waiting for draft<br>ETA 2019 Q4 –2020 Q1 | IVDR |
| 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 | | IVDR/MDR |
| **Procedure packs** | | | | | |
| Internal | Q&A | MedTech Europe | Q&A on procedure packs (transition, labelling, PMS, sterilization etc.) ***(new)*** | ETA 2019 Q4 | MDR |
| External | Guidance | MDCG | Guidance on UDI for systems and procedure packs (MDCG 2018-3) | **2018 October** | MDR |
| External | Guidance | MDCG | Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs (MDCG 2018-4) | **2018 October** | MDR |
| **Person Responsible for Regulatory Compliance (PRRC)** | | | | | |
| External | Guidance | MDCG | MDCG-7 on the Person Responsible for Regulatory Compliance (PRRC) Role referred to in IVDR/MDR Article 15 ***(new)*** | **2019 June** | IVDR/MDR |
| **Commission fact sheets** | | | | | |

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| External | Rolling plan | European Commission | MDR and IVDR implementation rolling plan ***(new)*** | **2019 August** | 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 |
| External | Factsheet | European Commission | Factsheet for healthcare professionals and health institutions ***(new)*** | **2019 June** | IVDR/MDR |
| **Other** | | | | | |
| External | Training material | MedTech Europe | Impact on distributors | **2017 November** | IVDR/MDR |
| External | Training material | MedTech Europe | IVDR Flowchart | **2017 December** | IVDR |
| External | Training material | MedTech Europe | MDR Flowchart | **2017 December** | 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 | Q&A on documentation which may be required to be provided by the manufacturer under the MDR. | **2018 October** | MDR |

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| 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 | 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 |
| Internal | Q&A | MedTech Europe | MTE internal Q&A series to support MD Regulation implementation (implant cards, hazardous substances) | **2018 December** | MDR |
| Internal | Training material | MedTech Europe | IVDR/MDR implications for Quality Management Systems webinar and slides | **2018 April** | 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 |
| External | Guidance | European Commission / MDCG-Market Surveillance working group | Guidance Note for Manufacturers of Class I Medical Devices ***(new)*** | In drafting phase<br>ETA 2019 Q4 | MDR |
| External | Implementing Regulation | European Commission | Reprocessing and Reuse of Single-Use Medical Devices - MedTech Europe Comments to the draft MDR Common Specifications, submitted in August 2019 ***(new)*** | In drafting phase<br>ETA 2019 Q4 | MDR |
| External | Guidance | MDCG | MDCG 2019-3 Interpretation of Article 54(2)b | **2019 March** | MDR |