# Ongoing/planned guidance development and deliverables of MDCG Subgroups – March 2024*

**This is not an exhaustive list of ongoing work performed by MDCG Subgroups*

| Scope | Group Deliverables | Consult prior to MDCG** | Planned MDCG Endorsement | Status |
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| *** Stakeholders are observers in 11 MDCG subgroups and are consulted on a regular basis; further to that other MDCG subgroups are consulted as indicated* | | | | |
| **1. Notified Bodies Oversight (NBO)[1]** | | | | |
| MDR + IVDR | *Q&A on requirements notified bodies – update of MDCG 2019-6* | NBCG-Med and all MDCG stakeholders as needed | 2024 | Permanent NBO Work Item - ongoing |
| MDR+IVDR | *Update of best practice guidance on designation and notification (MDCG 2022-13), including extension of scope* | NBCG-Med | Q2 2024 | Ongoing |
| MDR + IVDR | *Revision of NBOG F 2017-5 and -6 (PAR forms)* | NBCG-Med | Q2 2024 | Ongoing |
| MDR + IVDR | *PAR forms for re-assessment* | NBCG-Med | Q2 2024 | Ongoing |
| MDR + IVDR | *Corrective and Preventive Action plan (form)* | NBCG-Med | Q2 2024 | Ongoing |
| MDR + IVDR | *Update of best practice guidance on the information required for the conformity assessment bodies' personnel involved in conformity assessment activities (NBOG BPG 2017-2)* | NBCG-Med | 2024 | Ongoing |

[1] Stakeholders are not part of this group as it covers requirements set out by designating authorities specifically for notified bodies; stakeholders are consulted on mature and final drafts.

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| MDR | *Notified Body Technical Documentation Assessment Report* | Notified bodies and relevant MDCG Subgroups | 2024<br><br>PSUR section to be delivered as a first step | Ongoing |
| MDR + IVDR | *Revision of MDCG 2019-13 Guidance on sampling of devices for the assessment of the technical documentation* | MDCG Stakeholders and relevant MDCG subgroups | 2024 | Ongoing |
| IVDR | *Minor revision of MDCG 2021-14* | NBCG-Med, MDCG Stakeholders and IVD | 2024 | Ongoing |
| MDR | *Guidance on "appropriate surveillance" according to Article 120 (3) MDR* | MDCG Stakeholders and MS | Q2 2024 | Ongoing |
| 2. Standards | | | | |
| MDR + IVDR | *Extension and improvement of the MDCG guidance document on standardisation for medical devices endorsed and published in April 2021 (MDCG 2021-5)* | TBD | Q2 2024 | Ongoing |
| 3. Clinical Investigations and Evaluation (CIE) | | | | |
| MDR | *Clinical investigation – Q&A document* | N/A | End 2024 | Ongoing |
| MDR | *Contingency approach to exchange information according to Article 76(3) MDR in absence of EUDAMED* | N/A | As needed | Ongoing |

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| MDR | *Update of the clinical evaluation guidance* | N/A | Q3 2024 | Ongoing |
| MDR | *Update of the MDCG 2019-9 - Rev.1 Summary of safety and clinical performance* | N/A | Q1 2024 | Ongoing |
| MDR | *Guidance on content of Investigator's Brochure for clinical investigations conducted under (EU) regulation 2017/745 (MDR)* | N/A | Q1 2024 | Ongoing |
| 4. | Post-Market Surveillance and Vigilance (PMSV) | | | |
| MDR + IVDR | *Update MIR form, MIR PDF file, MIR Helptext and related documents* | IVD | Q2 2024 | Ongoing |
| MDR + IVDR | *Revision of MIR Q&A document* | IVD | Q2 2024 | Ongoing |
| MDR + IVDR | *Revision of Field Safety Corrective Action form* | IVD | Q3 2024 | Ongoing |
| IVDR | *Extension of PSUR guidance IVDR* | IVD, MS, NBO | Q3 2024 | Ongoing |
| IVDR | *Extension of Q&A documents on Vigilance terms and concepts to IVDR requirements* | IVD, NBO | Q2 2024 | Ongoing |
| MDR + IVDR | *Guidance on Post-Market Surveillance* | MS / IVD | Q2 2024 | Ongoing |
| MDR | *MDR Vigilance guidance on implementation of Articles 87 to 90 MDR* | MS /IVD | Q2 2024 | Ongoing |

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| MDR + IVDR | *Revision of Trend report and related documents* | MS / IVD | Q2 2024 | Ongoing |
| MDR + IVDR | *DSVG for transvaginal urogynaecological surgical mesh implants* | N/A | Q1 2024 | Ongoing |
| **5. Market Surveillance (MS)[2]** | | | | |
| MDR + IVDR | *Guidance document for manufacturers of custom made & adaptable devices* | NTE | TBD | Postponed until 2025 |
| **6. Borderline & Classification (B&C)** | | | | |
| MDR | *Minor revision of classification guidance MDCG 2021-24* | N/A | Q3 2024 | Ongoing |
| MDR | *Exploratory paper on qualification of products specifically intended for the cleaning, disinfection or sterilisation of devices* | N/A | Q2 2024 | Pending |
| MDR + IVDR | *Participate in Helsinki procedure and publish the B&C manual* | IVD, NT | Continuous | Ongoing |
| MDR + IVDR | *Procedures for notification of decision on dispute* | IVD | Q4 2024 | Ongoing |
| **7. New Technologies** | | | | |
| MDR + IVDR | *Legal status of app providers* | MS | Q4 2024 | Ongoing |
| MDR + IVDR | *Targeted revision of MDCG 2019-11* | B&C | Q4 2024 | Ongoing |
| MDR + IVDR | *FAQ on Interplay between MDR/IVDR and AIA* | As relevant | Q4 2024 | To be launched |

[2] Stakeholders are not part of this group as it covers requirements set out by competent authorities; stakeholders are consulted on mature and final drafts.

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| **8. Eudamed** | | | | |
| | *N/A* | | | |
| **9. Unique Device Identification (UDI)** | | | | |
| MDR | *Guidance on Master UDI-DI* | UDI | Q2 2024 | Ongoing |
| **10. International Matters** | | | | |
| | *N/A* | | | |
| **11. In Vitro Diagnostic Medical Devices (IVD)** | | | | |
| IVDR | *Common specifications for hepatitis E, Plasmodium, Toxoplasma and arboviruses* | N/A | Q2 2024 | Ongoing |
| IVDR | *Questions and Answers document on performance studies* | CIE | 2024 | Ongoing |
| IVDR | *Template and guidance for safety reporting in performance studies under IVDR* | CIE | 2024 | Ongoing |
| IVDR | *Minor revision of MDCG 2020-16* | B&C | Q1 2024 | Ongoing |
| IVDR | *Guidance on IVD borderline issues* | B&C | Q1 2024 | Ongoing |
| IVDR | *Guidance on Research Use Only devices* | N/A | Q4 2024 | Ongoing |
| IVDR | *Analysis of IVDR in context of hypothetical scenarios of an urgent response to a health crisis* | N/A | 2024 | Ongoing |

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| IVDR | *Minor revision of MDCG 2021-14 – Explanatory note on IVDR codes* | NBO | 2024 | Ongoing |
| IVDR | *Q&A/guidance on distance sales* | Joint with MSWG | Q3 2024 | Ongoing |
| IVDR | *Minor revision of MDCG 2023-1 – Health institution exemption (definition of 'health institution')* | MSWG | Q4 2024 | Ongoing |
| 12. Nomenclature | | | | |
| MDR + IVDR | *FAQ on EMDN* | N/A | Q3 2024 | Ongoing |
| MDR + IVDR | *Tool for EMDN definitions* | N/A | 2025 | Ongoing |
| 13. Annex XVI | | | | |
| MDR | / | / | / | / |
| Other | | | | |
| MDR | *Guidance on certificates under conditions* | NBO and CIE | 2024 | Ongoing – Task Force established under MDCG |
| MDR | *Guidance for manufacturers and notified bodies on the application of clinical evaluation requirements to orphan devices in view of their certification in accordance with the MDR.* | NBO, CIE, stakeholders of orphan device taskforce | 2024 | Ongoing – Task Force established under MDCG |
| MDR | *Revision of MDCG 2021-25 'Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC* | NBO, MS, PMSV, MDCG stakeholders | 2024 | Ongoing – Task Force established under MDCG |