

MDCG Subgroups / Working Groups, and their guidance and other documents (updated 6-12-2024)

Number. Name	Guidance and other documents in support of the MDR and IVDR	Endorsed and published	MDCG 2019-15 rev.1
		Planned	Revision
		Proposed for archiving	MDCG 2020-2 rev.1
Medical Device Coordination Group (MDCG)	<p>MDCG 2019-15 rev.1 Guidance notes for manufacturers of class I medical devices</p> <p>MDCG 2020-2 rev.1 Class I transitional provisions under Article 120 (3 and 4) - (MDR)</p> <p>MDCG 2021-25 rev.1 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 - Revision</p> <p>MDCG 2022-11 rev.1 MDCG Position Paper: Notice to manufacturers to ensure timely compliance with MDR and IVDR requirements</p> <p>MDCG 2022-14 Position Paper: Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDRs</p> <p>MDCG 2022-18 MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate</p> <p>MDCG 2024-16 Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices</p> <p>Guidance on certificates under conditions</p> <p>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</p>		
1. Notified bodies oversight (NBO)	<p>NBOG BPG 2017-2 Best practice guidance on the information required for personnel involved in conformity assessment - Update</p> <p>NBOG F 2017-7 Review of qualification for the authorisation of personnel (MDR)</p> <p>NBOG F 2017-8 Review of qualification for the authorisation of personnel (IVDR)</p> <p>MDCG 2018-8 Guidance on content of the certificates, voluntary certificate transfers</p> <p>MDCG 2019-6 rev.4 Questions and answers: Requirements relating to notified bodies - Update</p> <p>MDCG 2019-10 rev.1 Application of transitional provisions concerning validity of certificates issued in accordance to the directives</p> <p>MDCG 2019-12 Designating authority's final assessment form: Key information (EN)</p> <p>MDCG 2019-13 Guidance on sampling of devices for the assessment of the technical documentation - Revision</p> <p>MDCG 2019-14 Explanatory note on MDR codes</p> <p>MDCG 2020-3 rev.1 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD</p> <p>MDCG 2020-4 Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions</p> <p>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 (EU) 920/2013</p> <p>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</p> <p>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)</p> <p>MDCG 2020-17 Questions and Answers related to MDCG 2020-4: “Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions”</p> <p>MDCG 2021-14 Explanatory note on IVDR codes - Revision</p> <p>MDCG 2021-15 Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices regulation (MDR)</p> <p>MDCG 2021-16 Application form to be submitted by a conformity assessment body when applying for designation as notified body under the in vitro diagnostic devices regulation (IVDR)</p> <p>MDCG 2021-17 Applied-for scope of designation and notification of a conformity assessment body - Regulation (EU) 2017/745 (MDR)</p> <p>MDCG 2021-18 Applied-for scope of designation and notification of a conformity assessment body - Regulation (EU) 2017/746 (IVDR)</p> <p>MDCG 2021-23 Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746</p> <p>MDCG 2022-4 rev.2 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD</p> <p>MDCG 2022-13 rev.1 Designation, re-assessment and notification of conformity assessment bodies and notified bodies</p>		

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	<p>MDCG 2022-17 MDCG position paper on “hybrid audits”</p> <p>MDCG 2023-2 List of Standard Fees</p> <p>MDCG 2024-6 Preliminary re-assessment review (PRAR) form template (MDR)</p> <p>MDCG 2024-7 Preliminary assessment review (PAR) form template (MDR)</p> <p>MDCG 2024-8 Preliminary assessment review (PAR) form template (IVDR)</p> <p>MDCG 2024-9 Preliminary re-assessment review (PRAR) form template (IVDR)</p> <p>MDCG 2024-12 Corrective and preventive action (CAPA) plan assessment: guidance and templates for conformity assessment bodies, notified bodies, designating authorities, and joint assessment teams</p> <p>Notified Body Technical Documentation Assessment Report</p>		
2. Standards	MDCG 2021-5 rev.1 Guidance on standardisation for medical devices		
3. Clinical investigation and evaluation (CIE)	<p>MDCG 2019-3 rev.1 Clinical evaluation consultation procedure exemptions - Interpretation of article 54(2)b</p> <p>MDCG 2019-9 rev.1 Summary of safety and clinical performance - Update</p> <p>MDCG 2020-5 Guidance on clinical evaluation - Equivalence - Update</p> <p>MDCG 2020-6 Guidance on sufficient clinical evidence for legacy devices</p> <p>MDCG 2020-7 Guidance on PMCF plan template</p> <p>MDCG 2020-8 Guidance on PMCF evaluation report template</p> <p>MDCG 2020-10 rev.1 Guidance on safety reporting in clinical investigations</p> <p>MDCG 2020-13 Clinical evaluation assessment report template</p> <p>MDCG 2021-6 rev.1 Regulation (EU) 2017/745 - Questions & Answers regarding clinical investigation</p> <p>MDCG 2021-8 Clinical investigation application/notification documents</p> <p>MDCG 2021-20 Instructions for generating CIV-ID for MDR Clinical Investigations</p> <p>MDCG 2021-28 Substantial modification of clinical investigation under Medical Device Regulation</p> <p>2023/C 163/06 Commission Guidance on the content and structure of the summary of the clinical investigation report</p> <p>MDCG 2023-7 Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR and on sufficient levels of access to data needed to justify claims of equivalence</p> <p>MDCG 2024-3 Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices</p> <p>MDCG 2024-5 Guidance on the Investigator’s Brochure content</p> <p>MDCG 2024-10 Clinical evaluation of orphan medical devices</p> <p>MDCG 2024-15 Guidance on the publication of the clinical investigation reports and their summaries in the absence of EUDAMED</p> <p>Clinical investigation - Q&A document</p> <p>Contingency approach to exchange information according to Article 76(3) MDR in absence of EUDAMED</p>		
4. Post-market surveillance and vigilance (PMSV)	<p>MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745</p> <p>MDCG 2023-3 rev.1 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746</p> <p>MDCG 2024-1 Device Specific Vigilance Guidance (DSVG) Template</p> <p>MIR form, MIR PDF file, MIR Helptext and related documents - Update</p> <p>MIR Q&A document - Revision</p> <p>Field Safety Corrective Action form - Revision</p> <p>PSUR guidance IVDR - Extension</p> <p>Q&A documents on Vigilance terms and concepts to IVDR requirements - Extension</p> <p>Guidance on Post-Market Surveillance</p> <p>MDR Vigilance guidance on implementation of Articles 87 to 90 MDR</p> <p>Trend report and related documents - Revision</p>		
5. Market Surveillance (MS)	<p>MDCG 2019-8 v2 Guidance document implant card on the application of Article 18 Regulation (EU) 2017/745 on medical devices</p> <p>MDCG 2019-7 rev.1 Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a ‘person responsible for regulatory compliance’ (PRRC)</p> <p>MDCG 2020-9 Regulatory requirements for ventilators and related accessories</p>		

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	<p>MDCG 2021-3 Questions and Answers on Custom-Made Devices</p> <p>MDCG 2021-7 Notice to manufacturers and authorised representatives on the impact of genetic variants on SARS-COV-2 in vitro diagnostic medical devices</p> <p>MDCG 2021-11 Guidance on Implant Card - Device types</p> <p>MDCG 2021-26 Q&A on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746</p> <p>MDCG 2021-27 rev.1 Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746</p> <p>MDCG 2022-16 Guidance on Authorised Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746</p> <p>MDCG 2023-1 Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 - Revision</p> <p>Guidance document for manufacturers of custom made & adaptable devices</p>		
6. Borderline and classification (B&C)	<p>Helsinki Procedure for borderline and classification under MDR & IVDR</p> <p>Manual on borderline and classification under Regulations (EU) 2017/745 and 2017/746 v3</p> <p>MDCG 2021-24 Guidance on classification of medical devices - Revision</p> <p>MDCG 2022-5 rev.1 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices</p> <p>MDCG 2024-13 Regulatory status of ethylene oxide (EtO) intended for the sterilisation of medical devices</p> <p>Exploratory paper on qualification of products specifically intended for the cleaning, disinfection or sterilisation of devices</p>		
7. New technologies	<p>MDCG 2019-11 Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746 - Revision</p> <p>MDCG 2019-16 rev.1 Guidance on cybersecurity for medical devices</p> <p>MDCG 2020-1 Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software</p> <p>MDCG 2023-4 Medical Device Software (MDSW) - Hardware combinations Guidance on MDSW intended to work in combination with hardware or hardware components</p> <p>Legal status of app providers</p> <p>FAQ on Interplay between MDR/IVDR and AIA</p>		
8. EUDAMED	<p>MDCG 2019-4 Timelines for registration of device data elements in EUDAMED</p> <p>MDCG 2019-5 Registration of legacy devices in EUDAMED</p> <p>MDCG 2020-15 MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States</p> <p>MDCG 2021-1 rev.1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional</p> <p>MDCG 2021-13 rev.1 Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR</p> <p>MDCG 2022-12 Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices)</p>		
9. Unique Device Identification (UDI)	<p>MDCG 2018-1 rev.4 Guidance on basic UDI-DI and changes to UDI-DI</p> <p>MDCG 2018-3 rev.1 Guidance on UDI for systems and procedure packs</p> <p>MDCG 2018-4 Definitions/descriptions and formats of the UDI core elements for systems or procedure packs</p> <p>MDCG 2018-5 UDI assignment to medical device software</p> <p>MDCG 2018-6 Clarifications of UDI related responsibilities in relation to article 16</p> <p>MDCG 2018-7 Provisional considerations regarding language issues associated with the UDI database</p> <p>MDCG 2019-1 MDCG guiding principles for issuing entities rules on basic UDI-DI</p> <p>MDCG 2019-2 Guidance on application of UDI rules to device-part of products referred to in article 1(8), 1(9) and 1(10) of Regulation 745/2017</p> <p>MDCG 2020-18 MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers</p> <p>MDCG 2021-9 MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers</p> <p>MDCG 2021-10 The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices</p> <p>MDCG 2021-19 Guidance note integration of the UDI within an organisation's quality management system</p> <p>MDCG 2022-7 Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746</p> <p>MDCG 2024-14 Guidance on the implementation of the Master UDI-DI solution for contact lenses</p> <p>Guidance on the implementation of the Master UDI-DI solution for spectacle frames, spectacle lenses and ready-made reading spectacles</p>		
10. International matters			
11. In vitro	<p>MDCG 2020-16 rev.3 Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 - Revision</p>		

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diagnostic medical devices (IVD)	<p>MDCG 2021-2 Guidance on state of the art of COVID-19 rapid antibody tests</p> <p>MDCG 2021-4 rev.1 Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746</p> <p>MDCG 2021-21 rev.1 Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices</p> <p>MDCG 2021-22 rev.1 Clarification on “first certification for that type of device” and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48(6) of Regulation (EU) 2017/746</p> <p>MDCG 2022-1 Notice to 3rd country manufacturers of SARS-CoV-2 in vitro diagnostic medical devices</p> <p>MDCG 2022-2 Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs)</p> <p>MDCG 2022-3 Verification of manufactured class D IVDs by notified bodies</p> <p>MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR</p> <p>MDCG 2022-8 Regulation (EU) 2017/746 - application of IVDR requirements to ‘legacy devices’ and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC</p> <p>MDCG 2022-9 rev.1 Summary of safety and performance template</p> <p>MDCG 2022-10 Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)</p> <p>MDCG 2022-15 Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD</p> <p>MDCG 2022-19 Performance study application/notification documents under Regulation (EU) 2017/746</p> <p>MDCG 2022-20 Substantial modification of performance study under Regulation (EU) 2017/746</p> <p>MDCG 2024-4 Safety reporting in performance studies of in vitro diagnostic medical devices under Regulation (EU) 2017/746</p> <p>MDCG 2024-11 Guidance on qualification of in vitro diagnostic medical devices</p> <p>Questions and Answers document on performance studies</p> <p>Guidance on IVD borderline issues</p> <p>Guidance on Research Use Only devices</p> <p>Analysis of IVDR in context of hypothetical scenarios of an urgent response to a health crisis</p> <p>Q&A/guidance on distance sales</p>		
12. Nomenclature	<p>MDCG 2018-2 Future EU medical device nomenclature - Description of requirements</p> <p>MDCG 2021-12 FAQ on the European Medical Device Nomenclature (EMDN) - Revision</p> <p>MDCG 2024-2 Procedures for the updates of the EMDN</p> <p>Tool for EMDN definitions</p>		
13. “Annex XVI” products	<p>MDCG 2023-5 Guidance on qualification and classification of Annex XVI products - A guide for manufacturers and notified bodies</p> <p>MDCG 2023-6 Guidance on demonstration of equivalence for Annex XVI products - A guide for manufacturers and notified bodies</p> <p>Q&A on transitional provisions for products without an intended medical purpose covered by Annex XVI of the MDR</p>		

Sources:

- Medical Device Coordination Group Working Groups https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en
- Guidance - MDCG endorsed documents and other guidance https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en