Ongoing/planned guidance development and deliverables of MDCG Subgroups – January 2025*

**This reflects the MDCG subgroups' Annual Work Programmes but it is not an exhaustive list of ongoing work performed by MDCG Subgroups*

Scope	Group Deliverables	Consult prior to MDCG**	Planned MDCG Endorsement	Status
*** 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	Q1 2025	Permanent NBO Work Item - ongoing
MDR + IVDR	*Clarification on the designation process of notified bodies according to Regulation (EU) 2024/1689 (AI Act)*	NBCG-Med	Q3 2025	Work to start in January 2025 It might require revision of existing guidance such us MDCG 2022-13, MDCG 2019-14 and MDCG 2021-14.
MDR +IVDR	*Clarification on the use codes according to Commission Implementing Regulation (EU) 2017/2185, including minor revision of MDCG 2021-14*	NBCG-Med, IVD WG and all MDCG stakeholders as needed	2025	Work on minor revision of MDCG 2021-14 ongoing. Work on other clarification to start. It might require revision of other existing guidance such us MDCG 2022-13 and MDCG 2019-14
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	2025	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.

MDR	*Notified Body Technical Documentation Assessment Report*	Notified bodies and relevant MDCG Subgroups	2025 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	2025	Ongoing
IVDR	*Guidance on "appropriate surveillance" according to Article 110 (3) IVDR*	IVD WG and NBCG-Med	Q2 2025	Ongoing
MDR + IVDR	*Model assessment plan for joint assessments*	NBCG-Med	2025	Ongoing
2. Standards				
	N/A			
3. Clinical Investigations and Evaluation (CIE)				
MDR	*Clinical investigation – Q&A document*	N/A	Q3 2025	Ongoing
MDR	*Update of the clinical evaluation guidance*	N/A	Q3 2025	Ongoing
MDR	*Update of the MDCG 2019-9 - Rev.1 Summary of safety and clinical performance*	N/A	Q2 2025	Ongoing
MDR	*Targeted update of CIE documents to ensure consistency*	NT	Q2/2025	Ongoing

4. Post-Market Surveillance and Vigilance (PMSV)				
MDR + IVDR	*Update MIR form, MIR PDF file, MIR Helptext and related documents*	IVD	Q1 2025	Ongoing
MDR + IVDR	*Revision of MIR Q&A document*	IVD	Q2 2025	Ongoing
MDR + IVDR	*Revision of Field Safety Corrective Action form*	IVD	Q2 2025	Ongoing
IVDR	*Extension of PSUR guidance IVDR*	IVD, MS, NBO	Q2 2025	To be re-launched.
MDR + IVDR	*Guidance on Post-Market Surveillance*	MS / IVD	Q1 2025	Ongoing
MDR	*MDR Vigilance guidance on implementation of Articles 87 and 89 MDR*	MS /IVD	Q4 2025	Ongoing
MDR + IVDR	*Revision of Trend report and related documents*	MS / IVD	Q2 2025	Ongoing
5. Market Surveillance (MS)[2]				
MDR + IVDR	*Guidance document for manufacturers of custom made & adaptable devices*	NTE	TBD	Postponed

[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.

6. Borderline & Classification (B&C)				
MDR	*Minor revision of classification guidance MDCG 2021-24*	N/A	Q3 2025	Ongoing
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	Q3 2025	Ongoing
7. New Technologies				
MDR + IVDR	*Legal status of app providers*	MS	Q2 2025	Ongoing, feedback from DSA colleagues received and engagement with market players ongoing.
MDR + IVDR	*Targeted revision of MDCG 2019-11*	B&C	Q1 2025	Ongoing
MDR + IVDR	*FAQ on Interplay between MDR/IVDR and AIA*	As relevant	Q2 2025	First meeting with AI Board subgroup on interplay took place in December 2024.
8. Eudamed				
	N/A			
9. Unique Device Identification (UDI)				
MDR	*Guidance on Master UDI-DI for spectacle frames, spectacle lenses and ready-to-wear reading spectacles*	N/A	Q2 2025	To be launched

10. International Matters				
	N/A			
11. In Vitro Diagnostic Medical Devices (IVD)				
IVDR	*Common specifications for hepatitis E, Plasmodium, Toxoplasma and arboviruses*	N/A	2025	Ongoing
IVDR	*Questions and Answers document on performance studies*	CIE	2025	Ongoing
IVDR	*Guidance on Research Use Only devices*	N/A	2025	Ongoing
IVDR	*Analysis of IVDR in context of hypothetical scenarios of an urgent response to a health crisis*	N/A	2025	Ongoing
IVDR	*Minor revision of MDCG 2021-14 – Explanatory note on IVDR codes*	NBO	2025	Ongoing
IVDR	*Q&A/guidance on distance sales*	Joint with MSWG	2025	Ongoing
IVDR	*Minor revision of MDCG 2023-1 – Health institution exemption (definition of 'health institution')*	MSWG	2025	Ongoing
IVDR	*Guidance on orphan IVDs*	IVD, CIE, NBO	Q4 2025	Ongoing (MDCG orphan device TF)
IVDR	*Revision of MDCG 2022-6 (significant changes under Art. 110 IVDR) and MDCG 2022-8 (legacy IVDs) to align with IVDR as amended by Reg. 2024/1860*	NBO	Q3 2025	To be launched

12. Nomenclature				
MDR + IVDR	*Tool for EMDN definitions*	N/A	2025	Ongoing
13. Annex XVI				
MDR	*N/A*			
Other				
MDR	*Guidance on certificates under conditions*	NBO and CIE	Q2 2025	Ongoing – Task Force established under MDCG