Ongoing guidance development and deliverables of MDCG Subgroups – March 2023*

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

Scope	Group Deliverables	Consult prior to MDCG**	Planned MDCG Endorsement	Additional Comments
*** Stakeholders are observers in 13 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*	Notified bodies	N/A	Permanent NBO Work Item
MDR+IVDR	*Updates of guidance documents and templates on the designation and re-assessment process*	Notified bodies	2023	This includes update of MDCG 2022-13
MDR + IVDR	*Updates of guidance documents and templates on qualification and authorisation of personnel*	Notified bodies	2024	Work started in 2022
MDR	*Notified Body Technical Documentation Assessment Report*	Notified bodies and relevant MDCG Subgroups	2023	Work started in 2022
MDR	*Revision of MDCG 2020-3 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*	MDCG Stakeholders and relevant MDCG subgroups	2023	
MDR + IVDR	*Revision of MDCG 2019-13 Guidance on sampling of devices for the assessment of the technical documentation*	MDCG Stakeholders and relevant	2023	

[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.

		MDCG subgroups		
2. Standards				
MDR + IVDR	*Updates of guidance document MDCG 2021-5 on standardisation for medical devices*	NBO, IVD	Q2 2023	
3. Clinical Investigations and Evaluation (CIE)				
MDR	*Clinical Investigation Report Summary Template*		Q1 2023	
4. Post-Market Surveillance and Vigilance (PMSV)				
MDR + IVDR	*Extension of guidance on Periodic Safety Update Report to IVDR requirements*	IVD, MS, NBO	Q3 2023	
MDR + IVDR	*Extension of Q&A documents on Vigilance terms and concepts to IVDR requirements*	IVD, NBO	Q3 2023	
MDR + IVDR	*Guidance on Post-Market Surveillance requirements*	MS / IVD	Q2 2023	
MDR + IVDR	*Extension of Q&A document on Vigilance terms and concepts to IVDR requirements* *MDR Vigilance guidance on Articles 87 to 90*	MS / IVD MS /IVD	Q3 2023 Q4 2023	Q&A document on Art 87 to 90 has been replaced by MDR Vigilance guidance
MDR + IVDR MDR + IVDR	*Development of harmonised reporting forms for incidents* *Revision of Trend report and associated files*	MS / IVD MS / IVD	Q2 2023 Q2 2023	

5.	**Market Surveillance (MS)[2]**			
MDR + IVDR	*Update MDCG 2021-27 Q&A on Importers & Distributors*	IVD	Q.2 2023	
MDR + IVDR	*Update MDCG 2021-26 Q&A on repackaging & relabelling activities under Article 16*	IVD	Q.2 2023	
MDR + IVDR	*Update MDCG 2019-7 of PRRC Guidance*	IVD	Q.2 2023	
6.	**Borderline & Classification (B&C)**			
	N/A			
7.	**New Technologies**			
MDR + IVDR	*Legal status of app providers*			To be updated AFTER Q2
MDR + IVDR	*Guidance on MDSW - Hardware combination systems*	B&C		To be updated AFTER Q2
8.	**Eudamed**			
	N/A			
9.	**Unique Device Identification (UDI)**			
MDR	*Guidance on Master UDI-DI*	UDI	Q3 2023	

[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.

10. International Matters				
	N/A			
11. *In Vitro* Diagnostic Medical Devices (IVD)				
IVDR	*Common specifications for hepatitis E class D devices*	N/A	Q4 2023	In progress
IVDR	*Common specifications for Plasmodium and Toxoplasma class D devices*	N/A	Q4 2023	In progress
IVDR	*Common specifications for arbovirus (Zika, West Nile Virus, Chikungunya, dengue) class D devices*	N/A	2024	In progress
IVDR	*Questions and Answers document on performance studies*	CIE	Q3 2023	In progress
IVDR	*Template and guidance for safety reporting in performance studies under IVDR*	CIE	Q3 2023	In progress
IVDR	*Minor revision of MDCG 2022-9 – Summary of Safety and Performance Template*	CIE	Q2 2023	Addition of specific points
IVDR	*Minor revision of MDCG 2020-16 – Classification of IVDs*	B&C	Q4 2023	Addition of specific points
IVDR	*Transposition of MEDDEV 2.14/1 – IVD borderline issues for use under IVDR*	B&C	Q2 2023	In progress
IVDR	*Poss. minor revision of MDCG 2022-10 – Interplay between CTR/IVDR*	Medicinal product authorities / B&C / CIE	Q2 2023	In progress
IVDR	*Analysis of IVDR in context of hypothetical scenarios of an urgent response to a health crisis*	N/A	Q2 2023	In progress

IVDR	*Minor revision of MDCG 2021-14 – Explanatory note on IVDR codes*	NBO	2023	In progress
12. Nomenclature				
MDR + IVDR	*Procedures for the annual and ad-hoc updates of the EMDN*	N/A		To be updated AFTER Q2
MDR + IVDR	*FAQ on EMDN*	N/A		To be updated AFTER Q2
MDR + IVDR	*Mapping EMDN-GMDN package*	N/A	N/A	The outcome of this exercise is highly dependent on level of cooperation ensured by GMDN.
13. Annex XVI				
MDR	*Guidance document on the use of equivalence criteria for Annex XVI products*	CIE, NBO	Q2 2023	
MDR	*Guidance document on the classification of Annex XVI products*	B&C	Q2 2023	
MDR	*Q&A document on the transitional provisions established by the Annex XVI common specifications*	/	Q1/2023	