

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
<i>** Stakeholders are observers in 13 MDCG subgroups and are consulted on a regular basis; further to that other MDCG subgroups are consulted as indicated</i>				
1. Notified Bodies Oversight (NBO)¹				
MDR + IVDR	<i>Q&A on requirements notified bodies – update of MDCG 2019-6</i>	Notified bodies	N/A	Permanent NBO Work Item
MDR+IVDR	<i>Updates of guidance documents and templates on the designation and re-assessment process</i>	Notified bodies	2023	This includes update of MDCG 2022-13
MDR + IVDR	<i>Updates of guidance documents and templates on qualification and authorisation of personnel</i>	Notified bodies	2024	Work started in 2022
MDR	<i>Notified Body Technical Documentation Assessment Report</i>	Notified bodies and relevant MDCG Subgroups	2023	Work started in 2022
MDR	<i>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</i>	MDCG Stakeholders and relevant MDCG subgroups	2023	
MDR + IVDR	<i>Revision of MDCG 2019-13 Guidance on sampling of devices for the assessment of the technical documentation</i>	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	<i>Updates of guidance document MDCG 2021-5 on standardisation for medical devices</i>	NBO, IVD	Q2 2023	
3. Clinical Investigations and Evaluation (CIE)				
MDR	<i>Clinical Investigation Report Summary Template</i>		Q1 2023	
4. Post-Market Surveillance and Vigilance (PMSV)				
MDR + IVDR	<i>Extension of guidance on Periodic Safety Update Report to IVDR requirements</i>	IVD, MS, NBO	Q3 2023	
MDR + IVDR	<i>Extension of Q&A documents on Vigilance terms and concepts to IVDR requirements</i>	IVD, NBO	Q3 2023	
MDR + IVDR	<i>Guidance on Post-Market Surveillance requirements</i>	MS / IVD	Q2 2023	
MDR + IVDR	<i>Extension of Q&A document on Vigilance terms and concepts to IVDR requirements</i>	MS / IVD	Q3 2023	Q&A document on Art 87 to 90 has been replaced by MDR Vigilance guidance
	<i>MDR Vigilance guidance on Articles 87 to 90</i>	MS /IVD	Q4 2023	
MDR + IVDR	<i>Development of harmonised reporting forms for incidents</i>	MS / IVD	Q2 2023	
MDR + IVDR	<i>Revision of Trend report and associated files</i>	MS / IVD	Q2 2023	

5. Market Surveillance (MS) ²				
MDR + IVDR	<i>Update MDCG 2021-27 Q&A on Importers & Distributors</i>	IVD	Q.2 2023	
MDR + IVDR	<i>Update MDCG 2021-26 Q&A on repackaging & relabelling activities under Article 16</i>	IVD	Q.2 2023	
MDR + IVDR	<i>Update MDCG 2019-7 of PRRC Guidance</i>	IVD	Q.2 2023	
6. Borderline & Classification (B&C)				
	<i>N/A</i>			
7. New Technologies				
MDR + IVDR	<i>Legal status of app providers</i>			To be updated AFTER Q2
MDR + IVDR	<i>Guidance on MDSW - Hardware combination systems</i>	B&C		To be updated AFTER Q2
8. Eudamed				
	<i>N/A</i>			
9. Unique Device Identification (UDI)				
MDR	<i>Guidance on Master UDI-DI</i>	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. <i>In Vitro</i> Diagnostic Medical Devices (IVD)				
IVDR	<i>Common specifications for hepatitis E class D devices</i>	N/A	Q4 2023	In progress
IVDR	<i>Common specifications for Plasmodium and Toxoplasma class D devices</i>	N/A	Q4 2023	In progress
IVDR	<i>Common specifications for arbovirus (Zika, West Nile Virus, Chikungunya, dengue) class D devices</i>	N/A	2024	In progress
IVDR	<i>Questions and Answers document on performance studies</i>	CIE	Q3 2023	In progress
IVDR	<i>Template and guidance for safety reporting in performance studies under IVDR</i>	CIE	Q3 2023	In progress
IVDR	<i>Minor revision of MDCG 2022-9 – Summary of Safety and Performance Template</i>	CIE	Q2 2023	Addition of specific points
IVDR	<i>Minor revision of MDCG 2020-16 – Classification of IVDs</i>	B&C	Q4 2023	Addition of specific points
IVDR	<i>Transposition of MEDDEV 2.14/1 – IVD borderline issues for use under IVDR</i>	B&C	Q2 2023	In progress
IVDR	<i>Poss. minor revision of MDCG 2022-10 – Interplay between CTR/IVDR</i>	Medicinal product authorities / B&C / CIE	Q2 2023	In progress
IVDR	<i>Analysis of IVDR in context of hypothetical scenarios of an urgent response to a health crisis</i>	N/A	Q2 2023	In progress

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



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