Ongoing guidance development and deliverables of MDCG Subgroups –April 2022*

**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	2022	Q2 2022: NBOG PBG 2017-1 Revision 1 to include re-assessment process
MDR + IVDR	*Updates of guidance documents and templates on qualification and authorisation of personnel*	Notified bodies	TBD	Work starting in 2022
MDR + IVDR	*Template List of standard fees*	Notified bodies and MDCG Stakeholders	2022	
IVDR	*Guidance on appropriate surveillance according to Article 110(3)*	IVD WG and MDCG Stakeholders	2022	
MDR	*Notified Body Technical Documentation Assessment Report*	Notified bodies and relevant MDCG Subgroups	2022	
MDR	*Revision of MDCG 2020-3 Guidance on significant changes regarding the transitional*	MDCG Stakeholders	2022	

[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.

	provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD	and relevant MDCG subgroups		
MDR + IVDR	*Position on the concept of "Hybrid audits" carried out by notified bodies, including definition*	Notified bodies	2022	
2. Standards				
MDR + IVDR	*Updates of guidance document MDCG 2021-5 on standardisation for medical devices*	NBO, IVD	Q3 2022	
MDR + IVDR	*"Cookbook" for harmonised standards*		Q2 2022	Proposed by CLC TC 62, not intended to become a MDCG-endorsed document
3. Clinical Investigations and Evaluation (CIE)				
MDR	*Clinical Investigation Report Summary Template*		2022	
4. Post-Market Surveillance and Vigilance (PMSV)				
MDR + IVDR	*Guidance on Periodic Safety Update Report requirements*		Q2 2022	PSUR for MDR to be later adapted for IVDR
MDR + IVDR	*Guidance on Post-Market Surveillance requirements*	MS	Q3 2022	Work to be coordinated with the Market Surveillance WG
MDR + IVDR	*Q&A document on Vigilance terms and concepts* *Q&A document on Art 87 to 90 on Vigilance requirements*		Q3 2022 Q3 2022	Task force work has been divided in 2 groups respectively on definitions and on Art 86-90 interpretation
MDR + IVDR	*Development of harmonised reporting forms for incidents*		Q2 2022	Several Task Forces on-going on the updating of the MIR form and the Trend report form

5. Market Surveillance (MS)[2]				
MDR + IVDR	*Authorised Representatives*	IVD	2022	
MDR + IVDR	*In-house manufacturers*	IVD	2022	
MDR + IVDR	*Update MDCG 2021-27 Q&A on Importers & Distributors*	IVD	Q.4 2022	
MDR + IVDR	*Update MDCG 2021-26 Q&A on repackaging & relabelling activities under Article 16*	IVD	Q.4 2022	
MDR + IVDR	*Update MDCG 2019-7 of PRRC Guidance*	TBD	Q.4 2022	
6. Borderline & Classification (B&C)				
7. New Technologies				
MDR + IVDR	*Legal status of app providers*		Q4 2022	
MDR + IVDR	*Guidance on MDSW - Hardware combination systems*	B&C	Q2 2022	
8. Eudamed				
IVDR	*Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional (IVDR)*	IVD	2022	IVDR Implementation

[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.

9. Unique Device Identification (UDI)				
MDR + IVDR	*Q&A on UDI*	N/A	2022	
10. International Matters				
	N/A			
11. *In Vitro* Diagnostic Medical Devices (IVD)				
IVDR	*SSP (Summary of Safety & Performance) template*	CIE	2022	Template in development
IVDR	*Qualification of assays used in clinical trials of medicinal products*	N/A	2022	In collaboration with competent authorities for medicinal products
IVDR	*In-house devices*	MS	2022	Joint with Market Surveillance MDCG sub-group, draft in preparation
IVDR	*Analysis of IVDR in context of hypothetical scenarios of an urgent response to a health crisis*	N/A	2022	In progress
IVDR	*Performance study application/notification form*	CIE	2022	Template in development
IVDR	*Guidance on significant changes referred to in Article 110(3) of the IVDR*	NBO	2022	With reference to MDCG 2020-3
IVDR	*Guidance on application of IVDR requirements to legacy devices and those placed on the market before DoA*	NBO, PMSV, MS	2022	With reference to MDCG 2021-5
IVDR	*Minor revision of MDCG 2021-22 – Clarification on "first certification for that type of device" and corresponding procedures to be followed by notified bodies*	N/A	2022	Addition of notes, based on experience collected so far

12. Nomenclature				
MDR + IVDR	*Procedures for the annual and ad-hoc updates of the EMDN*	N/A	Q2-Q3 2022	
MDR + IVDR	*FAQ on EMDN*	N/A	Q3 2022	
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	Q4 2022	
MDR	*Guidance document on the classification of Annex XVI products*	B&C	Q4 2022	