Ongoing guidance development and other relevant work within MDCG Subgroups – December 2020*

**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 –new questions to be added to MDCG 2019-6*	Notified bodies	Q1 2021	
MDR+IVDR	*Updates of guidance documents and templates on the designation and re-assessment process*	Notified bodies	2021	
MDR + IVDR	*Updates of guidance documents and templates on qualification and authorisation of personnel*	Notified bodies	2021	
MDR + IVDR	*Guidance on Certifications according to Article 16 MDR/IVDR)*		2021	Jointly with the Market Surveillance WG
MDR	*Guidance on appropriate surveillance according to Article 120(3)*		2021	
MDR	*Guidance on NB opinions on the conformity of the device part according to Article 117 MDR*	B&C	2021	
IVDR	*Explanatory note on codes*	IVD, notified bodies	Q1 2021	
IVDR	*Batch verification on class D IVDs*	IVD	Q1 2021	
MDR	*Guidance on clinical evaluation consultation procedure*	CIE, notified bodies	2021	

[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.

2. Standards				
MDR + IVDR	*MDR/IVDR Standardisation Request*	N/A	2021	New Commission Implementing Decision, under development
MDR + IVDR	*Guidance on standardisation in the medical devices field*	NBO	2020	
3. Clinical Investigations and Evaluation (CIE)				
MDR	*Q & A on clinical investigation*		2021	
MDR	*Clinical Investigation Application Template*	Eudamed	2021	
MDR	*Clinical Investigation Assessment Template*		2021	
MDR	*Clinical Investigation Report Summary Template*		2021	
4. Post-Market Surveillance and Vigilance (PMSV)				
MDR + IVDR	*Post-Market Surveillance requirements*	CIE	TBD	Work to be coordinated with the CIE WG and the Market Surveillance WG
MDR + IVDR	*Vigilance requirements*	CIE	2021	Task Force has met 2 times. Work to last until Q2 2021
MDR + IVDR	*Development of harmonised reporting forms for incidents*	CIE	2021	Several Task Forces on-going on the Periodic Safety Report (PSR), the Periodic Safety Update Report (PSUR) and the Trend report

5. Market Surveillance (MS)[2]				
MDR + IVDR	*Update of PRRC Guidance*	TBD	2021	
MDR + IVDR	*Authorised Representatives*	TBD	2021	
MDR + IVDR	*In-house manufacturers*	IVD	2021	
MDR + IVDR	*Guidelines on Re-labelling & Re-packaging*	NBO	2021	
MDR	*Q&A on Custom-Made & Adaptable Devices*	N/A	2021	Now under Ad-hoc Task Force of MDCG
MDR + IVDR	*Q&A on Importers & Distributors*	TBD	2021	
6. Borderline & Classification (B&C)				
MDR	*Borderline with medicinal products (including general guidance, definitions of pharmacological, immunological and metabolic means of action and diagnosis)*	NBO	2021	
MDR	*Classification of medical devices*	NBO / NET	2021	
7. New Technologies				
MDR + IVDR	*Legal status of app providers*		2020	
MDR + IVDR	*Artificial Intelligence under MDR/IVDR framework*	B&C	TBD	

[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.

8. EUDAMED				
MDR + IVDR	*Guidance on harmonised administrative practices and alternative technical solutions*		2021	
9. Unique Device Identification (UDI)				
MDR + IVDR	*Integration of UDI in manufacturers' QMS*	N/A	2021	
MDR + IVDR	*Guidelines on specific product types (contact lenses)*	N/A	2021	
MDR + IVDR	*Adaptation of Annexes to IMDRF N48 'UDI System Application Guide'*	N/A	2021	
10. International Matters				
MDR + IVDR	*Taking into account MDSAP for NB*	NBO	2020	
11. *In Vitro* Diagnostic Medical Devices (IVD)				
IVDR	*Performance evaluation*	CIE	2021	Comments received as part of stakeholder consultation
IVDR	*SSP (Summary of Safety & Performance) template and guidance*	CIE	TBD	
IVDR	*Transfer of Common Technical Specifications (IVDD) to Common Specifications (IVDR)*	N/A	2021	
IVDR	*Development of common specifications*	N/A	TBD	Draft CS almost finished for Kidd & Duffy, Chagas, syphilis, CMV and EBV, first draft available for SARS-CoV-2

IVDR	*Qualification of assays used in clinical trials of medicinal products*	N/A	TBD	In collaboration with competent authorities for medicinal products
IVDD	*Guidance on state of the art for COVID-19 antibody tests*	N/A	2020	Guidance in stakeholder consultation
IVDD	*Q&A on IVDs in context of COVID-19*	N/A	2020	FAQ on COVID tests for general audience
12. Nomenclature				
MDR + IVDR	*Rules and process for update of EMDN*	N/A	2020	
MDR + IVDR	*1st release of EMDN*	N/A	Q4 2020	
MDR + IVDR	*Rules for allocation of EMDN to UDI-DI*	UDI	Q1 2021	To be commenced
MDR + IVDR	*Procedures for the annual and ad-hoc updates of EMDN*	EUDAMED	Q1 2021	Commenced
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
MDR + IVDR	*Translation of EMDN*	N/A	TBD (validation)	Experts from MS to liaise with translators in the course of the translation exercise
MDR + IVDR	*List of EMDN terms to be used for implant card purposes*	UDI	2021	
13. Annex XVI				
MDR	*Common Specifications for devices listed in Annex XVI*			