Ongoing guidance development within MDCG Subgroups – July 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 Notified bodies – new questions to be added to the document already published*		2020	
IVDR	*Explanatory note on codes*	IVD	2020	
IVDR	*Batch verification on class D IVDs*	IVD	2020	
MDR	*Applicability of clinical evaluation consultation procedure*	CIE	2021	
MDR + IVDR	*Update of best practice guidance on the information required for the conformity assessment*		2021	
MDR + IVDR	*Update of best practice guidance on designation and notification*		2020	
MDR + IVDR	*Guidance document on the re-assessment process*		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	*Standardisation Request*	N/A	2021	Adopted by COM on 15 May 2020, rejected by CEN-CENELEC on 16 June 2020; procedure to be restarted
MDR + IVDR	*Guidance on specific aspects of medical devices standardisation*	NBO	TBD	
3. Clinical Investigations and Evaluation (CIE)				
MDR	*Clinical evaluation assessment report template*	NBO	Q3 2020	
MDR	*Q & A on clinical investigation*		2020	
4. Post-Market Surveillance and Vigilance (PMSV)				
MDR + IVDR	*Post-Market Surveillance requirements*	CIE	TBD	Task Force to complete the tasks under development by CIE and MS subgroups
MDR + IVDR	*Vigilance requirements*	CIE	TBD	Task Force has met 2 times. Work to last until Q2 2021
MDR + IVDR	*Development of harmonised reporting forms for incidents*	CIE	TBD	Several Task Forces on-going on PSR and PSUR
5. Market Surveillance (MS)[2]				
MDR + IVDR	*Update of PRRC Guidance*	TBD	2020	
MDR + IVDR	*Authorised Representatives*	TBD	2021	

[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.

MDR + IVDR	*In-house manufacturers*	IVD	TBD	Task force to be set up
MDR + IVDR	*Guidelines on Re-labelling & Re-packaging*	NBO	2020	Joint Task Force with NBO to be set up
MDR	*Q&A on Custom-Made & Adaptable Devices*	N/A	2020	
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	Q3 2020	
MDR	*Classification of medical devices*	NBO / NET	Q3 2020	
7. New Technologies				
MDR + IVDR	*Legal status of app providers*		Q4 2020	
MDR + IVDR	*Artificial Intelligence under MDR/IVDR framework*		TBD	Currently in the stage of preliminary discussions
8. EUDAMED				
MDR + IVDR	*Guidance on harmonised administrative practices and alternative technical solutions*	EUDAMED	Q3-2020	
MDR + IVDR	*Position paper on the use of the Actor Registration Module in Member States*	N/A	Q3-2020	
9. Unique Device Identification (UDI)				
MDR + IVDR	*Integration of UDI in manufacturers' QMS*	N/A	2020	

MDR + IVDR	*Guidelines on specific product types (contact lenses)*	N/A	2021	
MDR + IVDR	*Endorsement of Annexes to IMDRF N48 'UDI System Application Guide'*	N/A	2020	
MDR + IVDR	*Guidance on linking several Basic UDI-DIs to the Summary of safety and clinical performance (SSCP) and product certificate registered in EUDAMED*	CIE, NBO	2020	
10. International Matters				
MDR + IVDR	*Taking into account MDSAP reports for NB surveillance*	NBO	Q2-3 2020	
11. In vitro Diagnostic Medical Devices (IVD)				
IVDR	*Classification of IVDs*	BC, NBO	Q2-3 2020	
IVDR	*Performance evaluation*	CIE, NBO	Q4 2020	
IVDR	*SSP (Summary of Safety & Performance) template and guidance*	CIE, NBO	TBD	
IVDR	*Transfer of Common Technical Specifications (IVDD) to Common Specifications (IVDR)*	N/A	Q3 2020	
IVDR	*Development of new common specifications*	N/A	Continuous	
IVDR	*Qualification of assays used in clinical trials of medicinal products*	N/A	TBD	In collaboration with competent authorities for medicinal products
12. Nomenclature				
MDR + IVDR	*Rules and process for update of EMDN*	N/A	Q4 2020	

MDR + IVDR	*1st release of EMDN*	N/A	Q4 2020	
MDR + IVDR	*Rules for EMDN assignment*	UDI	~~Q~~Q4 2020	
MDR + IVDR	*Translation of EMDN*	N/A	TBD (validation)	Extraordinary revision currently being processed in three batches. Batch 1 on all IVD EMDN codes have been completed and translated into all EU languages. Batch 2 is currently under translation, whereas Batch 3 is still pending.
MDR + IVDR	*List of EMDN terms to be used for implant card purposes*	UDI	Q4 2020	
13. Annex XVI				
MDR	*Common Specifications for devices listed in Annex XVI*	B&C	Q1 2021	