

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
<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 –new questions to be added to MDCG 2019-6</i>	Notified bodies	Q1 2021	
MDR+IVDR	<i>Updates of guidance documents and templates on the designation and re-assessment process</i>	Notified bodies	2021	
MDR + IVDR	<i>Updates of guidance documents and templates on qualification and authorisation of personnel</i>	Notified bodies	2021	
MDR + IVDR	<i>Guidance on Certifications according to Article 16 MDR/IVDR)</i>		2021	Jointly with the Market Surveillance WG
MDR	<i>Guidance on appropriate surveillance according to Article 120(3)</i>		2021	
MDR	<i>Guidance on NB opinions on the conformity of the device part according to Article 117 MDR</i>	B&C	2021	
IVDR	<i>Explanatory note on codes</i>	IVD, notified bodies	Q1 2021	
IVDR	<i>Batch verification on class D IVDs</i>	IVD	Q1 2021	
MDR	<i>Guidance on clinical evaluation consultation procedure</i>	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	<i>MDR/IVDR Standardisation Request</i>	N/A	2021	New Commission Implementing Decision, under development
MDR + IVDR	<i>Guidance on standardisation in the medical devices field</i>	NBO	2020	
3. Clinical Investigations and Evaluation (CIE)				
MDR	<i>Q & A on clinical investigation</i>		2021	
MDR	<i>Clinical Investigation Application Template</i>	Eudamed	2021	
MDR	<i>Clinical Investigation Assessment Template</i>		2021	
MDR	<i>Clinical Investigation Report Summary Template</i>		2021	
4. Post-Market Surveillance and Vigilance (PMSV)				
MDR + IVDR	<i>Post-Market Surveillance requirements</i>	CIE	TBD	Work to be coordinated with the CIE WG and the Market Surveillance WG
MDR + IVDR	<i>Vigilance requirements</i>	CIE	2021	Task Force has met 2 times. Work to last until Q2 2021
MDR + IVDR	<i>Development of harmonised reporting forms for incidents</i>	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	<i>Update of PRRC Guidance</i>	TBD	2021	
MDR + IVDR	<i>Authorised Representatives</i>	TBD	2021	
MDR + IVDR	<i>In-house manufacturers</i>	IVD	2021	
MDR + IVDR	<i>Guidelines on Re-labelling & Re-packaging</i>	NBO	2021	
MDR	<i>Q&A on Custom-Made & Adaptable Devices</i>	N/A	2021	Now under Ad-hoc Task Force of MDCG
MDR + IVDR	<i>Q&A on Importers & Distributors</i>	TBD	2021	
6. Borderline & Classification (B&C)				
MDR	<i>Borderline with medicinal products (including general guidance, definitions of pharmacological, immunological and metabolic means of action and diagnosis)</i>	NBO	2021	
MDR	<i>Classification of medical devices</i>	NBO / NET	2021	
7. New Technologies				
MDR + IVDR	<i>Legal status of app providers</i>		2020	
MDR + IVDR	<i>Artificial Intelligence under MDR/IVDR framework</i>	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	<i>Guidance on harmonised administrative practices and alternative technical solutions</i>		2021	
9. Unique Device Identification (UDI)				
MDR + IVDR	<i>Integration of UDI in manufacturers' QMS</i>	N/A	2021	
MDR + IVDR	<i>Guidelines on specific product types (contact lenses)</i>	N/A	2021	
MDR + IVDR	<i>Adaptation of Annexes to IMDRF N48 'UDI System Application Guide'</i>	N/A	2021	
10. International Matters				
MDR + IVDR	<i>Taking into account MDSAP for NB</i>	NBO	2020	
11. <i>In Vitro</i> Diagnostic Medical Devices (IVD)				
IVDR	<i>Performance evaluation</i>	CIE	2021	Comments received as part of stakeholder consultation
IVDR	<i>SSP (Summary of Safety & Performance) template and guidance</i>	CIE	TBD	
IVDR	<i>Transfer of Common Technical Specifications (IVDD) to Common Specifications (IVDR)</i>	N/A	2021	
IVDR	<i>Development of common specifications</i>	N/A	TBD	Draft CS almost finished for Kidd & Duffy, Chagas, syphilis, CMV and EBV, first draft available for SARS-CoV-2

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