



Medical Device Coordination Group (MDR/IVDR) DRAFT AGENDA

Date & time: **Monday 7 December 2020 (10:00 – 13:00 & 14:00 – 17:00)**
Tuesday 8 December 2020 (10:00 – 13:00)

Venue: **Videoconference meeting - connection details will be forwarded to confirmed participants MDCG members by email**

Monday 7 December 2020 (10:00 – 13:00)

1. Opening, adoption of the agenda
2. Implementation MDR / IVDR
 - 2.1 MDCG WGs - short update on their work
 - 2.2 CIE Work Programme
 - 2.3 Implementing acts
3. Notified bodies under MDR/IVDR
 - 3.1 MDCG recommendation on the draft designation of a notified body (tbc):
 - 3.1.1 Final assessment report of the designating authority and draft designation – summary presentation by the competent authority
 - 3.1.2 Final opinion of the joint assessment team – summary presentation by SANTE
 - 3.1.3 MDCG recommendation under Article 39(9) MDR
 - 3.2 Joint Assessments Progress Report
 - 3.3 Update on Joint assessments for designation of notified bodies during Covid-19 circumstances
 - 3.4 Discussion on conformity assessment performed by notified bodies in Covid-19 circumstances
4. Expert Panels - State of play on the setting up of Expert Panels
5. EUDAMED update

Monday 7 December 2020 (14:00 – 17:00)

- 6. IVDR Implementation – exchange of views
 - 6.1 Report of activities of IVD MDCG Working Group
 - 6.2 Joint Implementation Plan
 - 6.3 Discussion of specific IVDR transition issues
 - 6.4 Draft IVD MDCG WG Work Programme

7. COVID-19 and IVDs

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- 8. Custom made devices – for information
- 9. Draft MDCG Position Paper on UDI assignment rules for ophthalmic lenses and ready readers – for information
- 10. AOB
 - 10.1 European Health Union – information from the Commission
 - 10.2 CAMD (Competent Authorities for Medical Devices) – Update on activities by the Chair of CAMD

