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# Medical Device Coordination Group (MDR/IVDR) DRAFT AGENDA

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Date & time: **13 December 2019 (09:30 – 18:00)**

Venue: **Conference Centre Albert Borschette (CCAB) – room: 1.D  
36 rue Froissart, 1040 Brussels, Belgium**

*Please note points for endorsement: 5, 6 & 7*

*Also, please note that all the points concern common topics for MDR and IVDR, except for:*

- *7 – concerns MDR only*
- *10 – concerns IVDR only*

1. Opening, adoption of the agenda
2. Adoption of the minutes of the meeting held on 1 October 2019
3. Update by the European Commission including on MDCG activities
4. Notified bodies under MDR/IVDR – Joint Assessments Progress Report
5. Guidance on Clinical / Performance evaluation of software for endorsement
6. Guidance on Cybersecurity for endorsement
7. Guidance on Class I manufacturers for endorsement
8. Eudamed state of play and next steps
9. Ongoing Implementing Acts (update)
10. IVD specific topics (update)
  - 10.1. EU Reference Laboratories
  - 10.2. Common specifications
11. Expert panels (update)
  - 11.1. Applications received for the Call of Expression of Interest
  - 11.2. Preparatory work on a guidance document for consistent interpretation of criteria in Annex IX, point 5.1. c
12. AOB
  - 12.1. CAMD (Competent Authorities for Medical Devices)
    - 12.1.1. Updated on activities by the Chair of CAMD
    - 12.1.2. Operational Working Group
  - 12.2. Communication campaign