TERMS OF REFERENCE OF THE MDCG WORKING GROUP

WORKING GROUP ON CLINICAL INVESTIGATION AND EVALUATION (CIE)

1. Tasks and roles

CIE provides assistance to the MDCG on issues relating to clinical investigation and evaluation of medical devices in accordance with Regulation (EU) 2017/745 (MDR). In the field of its activities, the group prepares draft guidance, for endorsement by the MDCG.

In addition, CIE develops proposals for common specifications in respect of the clinical investigation, evaluation and post-market clinical follow-up, as referred to in Article 9 MDR.

2. Membership

Members/observers to CIE are experts appointed by Member States and third countries participating in the MDCG. Member States / third countries may appoint alternates.

Appointments are not time-limited. Any changes in the appointment shall be notified to the Commission without delay.

Stakeholders may participate in the open sessions of CIE either in the capacity of observers or following *ad hoc* invitations, in accordance with the Rules of Procedure of the MDCG.

3. Operation

CIE operates in accordance with the terms and rules applicable to the MDCG, unless specified otherwise in these Terms of Reference.

CIE shall be chaired by a representative of the Commission. Where appropriate, it may be co-chaired by a member of the working group. The group shall report to the MDCG.

The meetings are convened by the Chair.

CIE shall meet either in physical meetings or for audio- or videoconferences.

Physical meetings of the CIE take place at least twice a year.

Minutes on the discussion on each point on the agenda and on the positions delivered by the group shall be meaningful and complete.

CIE coordinates its activities with other MDCG working groups as appropriate.

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25 September 2018