TERMS OF REFERENCE OF THE MDCG WORKING GROUP

WORKING GROUP ON BORDERLINE & CLASSIFICATION

1. Tasks and roles

The Working Group on Borderline & Classification provides assistance to the MDCG on issues related to:

(i) qualification of a product as a medical device / an accessory for a medical device under Regulation (EU) 2017/745 (MDR), and *in-vitro* diagnostic medical device / an accessory for an *in-vitro* diagnostic medical device under Regulation (EU) 2017/746 (IVDR);
(ii) qualification of products without an intended medical purpose in accordance with Annex XVI MDR;
(iii) classification of medical devices in accordance with Annex VIII MDR and classification of *in-vitro* diagnostic medical devices in accordance with Annex VIII IVDR.

The group prepares draft guidance on qualification and classification, for endorsement by the MDCG. It provides a forum for an exchange of information and coordination of national practices as regards qualification and classification of devices, in accordance with the consultation mechanism – the so-called "Helsinki Procedure". The group prepares a compendium of qualification and classification entries following from the application of the "Helsinki Procedure" in the form of a "Manual on Borderline and Classification".

2. Membership

Members/observers to the group 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 the group either in the capacity of observers or following *ad hoc* invitations, in accordance with the Rules of Procedure of the MDCG.

3. Operation

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

The group 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.

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

Physical meetings of the group take place at least once a year. A teleconference takes place once per quarter.

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

The group provides support to and coordinates its activities with other MDCG working groups as appropriate.

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25 September 2018