TERMS OF REFERENCE OF THE MDCG WORKING GROUP

WORKING GROUP ON *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES (IVD)

1. Tasks and roles

The Working Group on *In-Vitro* Diagnostic Medical Devices (IVD) provides assistance to the MDCG on all IVD specific issues, in particular it develops and promotes homogenous application and implementation of Regulation (EU) 2017/746 (IVDR). It prepares draft guidance on IVD related issues for endorsement of the MDCG.

The group coordinates its activities with other MDCG working groups as appropriate and, whenever needed, provides them with input on IVD specific aspects of their work (such as in the field of classification, performance studies, performance evaluation and post-market performance follow-up of IVDs).

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 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.

The group coordinates its activities with other MDCG working groups as appropriate.

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25 September 2018