

## **TERMS OF REFERENCE OF THE MDCG WORKING GROUP**

### **WORKING GROUP ON INTERNATIONAL MATTERS**

#### **1. Tasks and roles**

The Working Group on International Matters provides assistance to the MDCG on any international issues related to medical devices and *in-vitro* diagnostic medical devices, in particular it monitors international regulation trends. In addition, the group coordinates formulation of common views and positions of EU Member States on harmonisation topics discussed within the International Medical Device Regulators Forum (IMDRF). The activities of the group take into account the positions, recommendations, and any relevant documents prepared by other working groups of the MDCG.

#### **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, in particular on IMDRF related matters.

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25 September 2018