

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

### **WORKING GROUP ON UNIQUE DEVICE IDENTIFICATION (UDI) AND DEVICE TRACEABILITY**

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

The group provides assistance to the MDCG on all issues related to introduction and operation of the Unique Device Identification system (UDI system) under Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR).

The group provides advice on all matters related to device identification and traceability, including implementation of the relevant provisions of the MDR on implant cards.

In the field of its activities, the group prepares draft guidance for endorsement by the MDCG, or an input for the delegated acts foreseen in the MDR and IVDR.

#### **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