

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

### **WORKING GROUP ON MARKET SURVEILLANCE**

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

The Working Group on Market Surveillance assists the MDCG in its endeavor to coordinate market surveillance. This includes the development and maintenance of a framework for a European market surveillance programme, with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 93 of Regulation (EU) 2017/745 on medical devices (MDR) and Article 88 of Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR).

The group deals, among others, with an analysis of: (i) the application and implementation of the general safety and performance requirements set out in Annex I of the MDR / Annex I of the IVDR; (ii) general obligations of economic operators laid down in Chapter II of the MDR / Chapter II of the IVDR; (iii) obligations of economic operators and conformity assessment with regard to products that do not require the involvement of notified bodies.

In the field of its activities, the group prepares draft guidance, for endorsement of the MDCG.

#### **2. Membership**

Members/observers to the group are experts appointed by Member States and third countries participating in the MDCG. They represent the competent authorities responsible for market surveillance. 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.

#### **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