

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

## **WORKING GROUP ON ANNEX XVI devices**

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

The Working Group on Annex XVI devices assists the MDCG in developing common specifications for those groups of products listed in Annex XVI of the Regulation (EU) 2017/745 for which a manufacturer claims only an aesthetic or another non-medical purpose.

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 for Annex XVI devices; (ii) general obligations of economic operators laid down in Chapter II of the MDR with reference to Annex XVI devices; (iii) development of guidance documents concerning application of requirements mentioned in point (i), with particular reference to qualification of products and technical aspects.

In the field of its activities the group prepares draft guidance for endorsement of the MDCG.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 list of groups of products without an intended medical purpose referred to in article 1(2) of Regulation (EU) 2017/745. 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 normally once 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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29 April 2019