

TERMS OF REFERENCE OF THE MDCG WORKING GROUP

WORKING GROUP ON STANDARDS

1. Tasks and roles

The Working Group on Standards provides assistance to the MDCG on issues relating to standardisation in the field of medical devices, in particular harmonised standards referred to in Article 8 of Regulation (EU) 2017/745 on medical devices (MDR) and Article 8 of Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR). In particular, the group deals with harmonised standards where problems or safety related issues are identified and makes proposals for solutions. In addition, it provides advice to the MDCG and other working groups on availability of harmonised standards in the context of preparation of common specifications referred to in Articles 9 MDR / 9 IVDR.

The group supports establishing a coordinated and more effective cooperation with the European and international standardisation organisations, in particular in the context of the International Medical Device Regulators Forum (IMDRF). It contributes to the development of proposals for standardisation requests to the European Standardisation Organisations.

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 annually.

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.

25 September 2018