

TERMS OF REFERENCE OF THE MDCG WORKING GROUP

WORKING GROUP ON NEW TECHNOLOGIES

1. Tasks and roles

The Working Group on New Technologies provides assistance to the MDCG on issues related to application of new and emerging technologies to medical devices under Regulation (EU) 2017/745 (MDR) and *in-vitro* diagnostic medical device under Regulation (EU) 2017/746 (IVDR), including software, apps and cybersecurity. In particular, the group analyses the adequacy of the existing regulatory framework in relation to those issues and technologies and, where challenges are identified, it provides recommendations to the MDCG.

The group contributes to the development of proposals for guidance and common specifications in the field as referred to in Article 9 of MDR/Article 9 of the IVDR.

The group elaborates proposals for the review of Commission Regulation (EU) 207/2012 on electronic instructions of use of medical devices.

The group continuously performs screening of the available sources for identification of novel, emerging technologies which inherit medical/clinical potential.

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.

25 September 2018