

**TERMS OF REFERENCE OF THE MDCG WORKING GROUP**  
**NOTIFIED BODIES OVERSIGHT (NBO)**

**1. Tasks and roles**

NBO provides assistance to the MDCG on issues relating to notified bodies and conformity assessments, with the aim of consistent, effective and harmonised application and implementation of Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR).

NBO provides a forum for sharing of experience and coordination of administrative practice among authorities responsible for notified bodies (the designating authorities), in accordance with Articles 48(1) MDR / 44(1) IVDR.

NBO prepares draft best practice documents and model forms relating to the activities of designating authorities, notified bodies and their conformity assessment activities, for endorsement of the MDCG.

NBO advises the Commission, at its request, on matters concerning the Coordination Group of Notified Bodies, as referred to in Articles 49 MDR / 45 IVDR.

**2. Membership**

Members/observers to the NBO are experts appointed by Member States and third countries participating in the MDCG. They represent the designating authorities. 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**

NBO operates in accordance with the terms and rules applicable to the MDCG, unless specified otherwise in these Terms of Reference.

NBO shall be chaired by a representative of the Commission. Where appropriate, it may be co-chaired by a member of the group. NBO shall report to the MDCG.

The meetings are convened by the Chair.

NBO shall meet either in physical meetings or for audio- or videoconferences.

Physical meetings of the NBO 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.

NBO coordinates its activities with other MDCG working groups as appropriate.

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25 September 2018