Intertek Medical Notified Body statement on remote audits under the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR).

The EU Commission published an informative notice 2021/C 8/01 on the 11th of January 2020 in the Official Journal on the application of the MDR[1] and IVDR[2] with regards to Notified Bodies' audits performed in the context of quality management system assessments. The Commission Notice describes the legal context of potential temporary extraordinary measures, including remote audits, under MDR and IVDR.

IMNB has in collaboration with the Notified Bodies trade association, TEAM-NB, worked on a position paper to seek a harmonized and risk-based approach on how this cumulative set of circumstances and conditions, as set out in the Commission Notice, could be met under the circumstances dictated by the COVID-19 global pandemic. Team-NB have shared their Position Paper on remote audits with the Commission and Designating Authorities. The authorities have communicated that they are working together on different levels (national, European) to achieve a Union-wide harmonised implementation of the Commission Notice 2021/C 8/01. The Team-NB paper is currently on hold as the authorities work to publish a harmonised approach, link https://www.team-nb.org/team-nb-have-shared-their-position-paper-on-remote-audits-with-the-commission-and-designating-authorities-the-authorities-have-communicated-that-they-are-working-together-on-different-levels-nation/.

IMNB is performing Impact assessment to its internal procedures in accordance with "*Commission Notice on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment the challenges in the implementation of Medical Device Regulation (MDR)[3] and In Vitro Diagnostic Device Regulation (IVDR)[4] for notified bodies during the COVID-19 global pandemic*", which was published on 11th of January 2020 in the Official Journal. IMNB is strongly encouraging all our clients to proceed towards MDR Application as soon as possible, independent of the output of above-mentioned efforts.

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.