The European Association
Medical Devices - Notified Bodies

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Team-NB statement

on MDR date of application postponement

Team NB, the European Association of Notified Bodies in the Medical Devices sector welcomes Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions.

The members of Team-NB are committed to contribute as much as possible to the fight against the corona pandemic. We are in constant interaction with EU Commission and national authorities on optimal ways to leverage our joint knowledge and expertise to contribute to the continued availability of medical devices indispensable to that fight.

We are aware that the corona pandemic massively increases the demand for certain vital medical devices. It is therefore important to avoid any potential difficulties or risks of shortages or delays in the availability of such devices. The adopted Regulation could be an important tool to achieve this goal, by allowing the continued availability of those vital medical devices for the European citizens under the current regulatory regime for one additional year, so until 26 May 2021.

However, next to the fight against the corona crisis, which rightly transcends everything else at the moment, EU health care systems also need to be assured, in the longer term, of a continuous flow of available medical devices in areas outside the scope of COVID-19 treatment and prevention.

Due to the postponement of date of application of the MDR by Regulation (EU) 2020/561, the grace period available for manufacturers to switch from the current legislation (AIMDD/MDD) to MDR has been shortened from 4 to 3 years. This has considerable consequences for the spread of Team-NB members' workload over the upcoming years.

Nevertheless, Team-NB members will do everything within their power to make the switch from AIMDD/MDD to MDR in the shortened transition period as smooth as possible. We call on medical device manufacturers and other stakeholders to pursue their original plans for this transitioning as much as possible under the given circumstances.