

Healthcare systems across Europe in need of accelerated implementation of the Medical Device Regulation

We, the undersigned, are committed to regulations that will ensure patient safety and continued access to medical devices for patients, healthcare professionals and healthcare systems in Europe.

On 26 May 2020, less than one year from now, the new Regulation for Medical Devices will enter into full effect. However, the new regulatory system will need to be fully functional months before this deadline, in order to enable the thousands of medical devices currently on the market to go through a mandatory 3-9 months re-certification process.

The timely functionality of the system is critical to guarantee the continued supply of devices to health institutions. But as of today, achieving this is very unlikely thereby putting patient care across Europe at risk.

There is a mechanism in the Regulation's transition process, sometimes referred to as the 'Grace Period,' that was intended to prevent these current challenges. However, this mechanism has two fundamental weaknesses:

- 1) Several healthcare-critical product categories are ineligible for the Grace Period, and no European solutions have been provided to keep these devices available after 26 May 2020, and
- 2) Even for those medical devices which are eligible, the Grace Period is not working in practice, because the certification bodies ('Notified Bodies') that exist today are unable to process all the files in time.

Immediate action is needed now to avoid severe disruption of product supply to patients and hospitals as well as to safeguard the innovation capacity of the sector in developing new life-saving and life-transforming technologies.

We thus call on the European Commission and Member States to accelerate the implementation of the regulatory system to prevent a "cliff-edge" scenario for patients, healthcare professionals, and healthcare systems in Europe.

Brussels, May 2019

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