



## Medical Devices: European Commission Intends to Postpone New MDR Regulation

Due to the COVID-19 crisis, the European Commission intends to postpone the date on which the regulation on medical devices enters into force by one year.

The new regulation on medical devices should actually come into force on May 26, 2020. Among other things, it lays down uniform and more stringent criteria for so-called "Notified Bodies" for the approval of medical devices and regulates the procedure for approving clinical trials of medical devices. In order to avoid a **shortening or any other interruption in the supply of medical devices** in the current tense situation, the European Commission will propose a moratorium of one year.

## And: Decisions on Harmonized Standards to Speed up Conformity Assessment Adopted

### Harmonized Standards

In addition, on March 24, 2020 the European Commission decided on harmonized standards, for example to ensure the supply of medical face masks and disinfection equipment.

These standards should enable a faster and more cost-effective procedure for the assessment of the required conformity. They concern products of key importance, such as medical face masks, surgical drapes and gowns as well as clean-air clothing or disinfectors.

Once these measures are implemented, medical device manufacturers and other economic operators concerned will be able to use these standards to meet the health and safety requirements of the three medical device directives

We will be happy to assist you with legal questions on topics related to medical devices!

### Stay well and safe!



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