

Commission publishes amendment to the rules on the designation and the surveillance of notified bodies for medical devices

On 19 May 2020, the Commission published the Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies

The amendment introduces changes to the rules on the renewal of designations and on the surveillance and monitoring of notified bodies under the Medical Devices Directive (Directive 93/42/EEC) and the Active Implantable Medical Devices Directive (Directive 90/385/EEC).

Those changes have been adopted in the context of COVID-19 and the recent postponement of the application of the Medical Devices Regulation.

The amended rules enable Member States to ensure that currently designated notified bodies can continue to operate until 25 May 2021. In addition, they allow for alternative surveillance and monitoring activities related to notified bodies that remain possible under current restrictions resulting from COVID-19.