New Regulation (EU) 2020|561 for medical devices

30.04.2020 | Worldwide

The **Regulation (EU) 2020/561** of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices is published on 24 April 2020 in the Official Journal of the European Parliament!

The main objective to the amendment is to postpone the date of application from 26 May 2020 to 26 May 2021. Along with this postponement other dates of applications of other provisions were adopted as well. Please find the official publication of the Amendment Regulation here: https://eur-lex.europa.eu/eli/reg/2020/561/oj

TUV Rheinland appreciated and supports the postponement. The measure gives medical device manufacturers the opportunity to fully focus all possible resources on the fight against the COVID-19 pandemic. Medical device manufacturers play an important role, but challenging role. It is critically important that medical devices remain compliant and continue to be available in the EU in order to avoid shortages or delays of certain medical devices during these circumstances. For this

reason, we will continue to be active, also during 2020, to develop new certification procedures in reference to Directive 93/42/EEC.

Beyond this situation, for all the Manufacturers intending to certify devices with MDR anyway, TÜV Rheinland would like to encourage its clients to keep in contact with the medical department in order to continue planning also the activities based on the Regulation 2017/745..

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