SARSTEDT

Geräte und
Verbrauchsmaterial
für Medizin
und Wissenschaft

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12. May 2022

Continuous availability of Sarstedt products, MDR 2017/745 and IVDR 2017/746

In connection with the change in the legal provisions for medical devices and in vitro diagnostic medical devices, we repeatedly receive queries from our customers concerning the availability and conformity of our products.

In the European Union, the new legal provisions entered into force by the two regulations 2017/745, referred to as the MDR, and 2017/746, referred to as the IVDR.

It is particularly important to note that the former legal provisions from the Medical Devices Directive and the In Vitro Diagnostic Medical Devices Directive continue(d) to remain valid in parallel for a transition period.

The legislator thus accommodates to extremely increased requirements, the considerable rise in the number of regulated products, and the capacities of manufacturers and Notified Bodies. The specified transition periods will last until May 2027, depending on the product class and certification status of the manufacturer. We can assure you that we have already been working continuously on the conversion to the new regulations for years and are gradually adapting products to the new requirements.

With regard to the IVDR transition periods, please note that SARSTEDT AG & Co. KG markets only in vitro diagnostic medical devices that will fall into IVDR classes A and/or A sterile in the future.

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For class A devices that are nonsterile products, the certificate of conformity in accordance with the IVDR will be provided as of 26 May 2022 at the latest and all applicable requirements of the IVDR will be met. A transition period will apply until 26 May 2027 for in-vitro-diagnostic devices of class A sterile. As a result of the gradual and continuous work, we will provide the corresponding proof of conformity for these products by this date at the latest.

By working intensively on this topic and continually adapting the declarations of conformity, while strictly observing the statutory time limits, we ensure that you have a continuous supply of medical devices and in-vitro-diagnostic medical devices which comply with all legal provisions.

Kind regards,

SARSTEDT AG & Co. KG

Jochen Hoffmann
Head of Quality Management