SARSTEDT

Geräte und
Verbrauchsmaterial
für Medizin
und Wissenschaft

SARSTEDT AG & Co. KG · Postfach 12 20 · 51582 Nümbrecht

Department: Quality Management
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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 are repeatedly receiving queries from our customers concerning the availability and conformity of our products.

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

Of note in particular is 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.

Lawmakers thus accommodate the greatly increased requirements, the considerable rise in the number of regulated products, and the capacities of manufacturers and notified bodies. The specified transition periods last until May 2027, depending on device class and certification status of the manufacturer.

We can assure you that we have already been working continuously for years on the changeover to the new rules and are gradually adapting / have already adapted products to the new requirements.

<u>Adaptation of IVDs:</u>

The adaptation of all Class A (non-sterile) IVD products to the IVDR is already fully completed. The certificate of conformity in accordance with the IVDR was provided no later than 26 May 2022 and all applicable requirements of the IVDR were met.
A transition period applies until 26 May 2027 for Class A (sterile) in vitro diagnostic medical devices. Through gradual and continuous work, we will provide the corresponding proof of conformity for these products by this date at the latest.

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Adaptation of Medical Devices:

The medical device certificates in compliance with Directive 93/42/EEC remain valid until the end of the period specified therein, but no later than 27 May 2024. The medical devices of SARSTEDT AG & Co. KG are currently marketed legally under the valid MDD certificate (Directive 93/42/EEC) with valid declarations of conformity. We will complete the corresponding MDR certification for the medical devices at the latest by the expiry date of the MDD certificate.

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

Kind regards,

S A R S T E D T A G & Co. KG
p.p.

Jochen Hoffmann
Head of Quality Management