Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 075349 0012 Rev. 01

Manufacturer:

Sartorius Stedim Biotech GmbH
August-Spindler-Str. 11
37079 Göttingen
GERMANY

Product Category(ies): class IIa non-active sterile and non-sterile syringe filters as injection filters and vent filters for removal of particles from sterile liquids or from sterile dry air and gases or for ultracleaning of air and gases or liquids for infusion, administration or introduction into the human body

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713178500

Valid from: 2020-04-07
Valid until: 2024-05-26

Date, 2020-04-07

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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A4 / 07.17