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 037584 0027 Rev. 01

Manufacturer:

Terumo Medical Products (Hangzhou) Co., Ltd.
M4-9-5 Hangzhou Economic &
Technological Development Zone
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Terumo Medical Products (Hangzhou) Co., Ltd.
M4-9-5 Hangzhou Economic &, Technological Development Zone,
310018 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

SAFEED Extension Tube,
Winged Infusion Set,
Three-way Stopcock,
Solution Administration Set for Infusion Pump,
Blood Administration Set for Infusion Pump

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.: SH19073EXT01

Valid from: 2019-10-08

Valid until: 2024-05-26

Date, 2019-10-08

Stefan Preiß
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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