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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 037584 0029 Rev. 02

Manufacturer:

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

SRN Manufacturer - CN-MF-000001640

Authorized Representative:

TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 037584 0029 Rev. 02

Report No.: SH2307303

Preceding Certificate No.: G10 037584 0029 Rev. 01

Valid from: 2024-01-09
Valid until: 2026-10-25

Date of Initial Issuance: 2021-10-26

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-01-09

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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No. G10 037584 0029 Rev. 02

Classification:	Class IIa
Device Group:	A0302 - EXTENSION LINES
Intended Purpose:	/

Classification:	Class IIa
Device Group:	A030101 - INFUSION CONTROLLERS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	A0703 - STOPCOCKS
Intended Purpose:	/

Classification:	Class IIa
Device Group:	A010102 - BUTTERFLY NEEDLES
Intended Purpose:	/

Classification:	Class IIa
Device Group:	A03010102 - INFUSION CONTROLLERS WITH FILTER (ALSO TRANSFUSION CONTROLLERS)
Intended Purpose:	/

Classification:	Class IIa
Device Group:	V030101 - THERMOMETERS
Intended Purpose:	/

The validity of this certificate depends on conditions and/or is limited to the following:	-n.a-

Revision History:

Rev.	Dated	Report	Description
00	2021-10-26	SH20073MDR	-
01	2023-12-29	SH2307303	Reduced: Device(s)/group of device(s) removed
02	2024-01-09	SH2307303	Supplemented: Device(s)/group of device(s) added

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