

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III



Registration No.: HZ 1594584-1

Manufacturer: **TERUMO EUROPE N.V.**
Interleuvenlaan 40
3001 Leuven
Belgium

EUDAMED Single
Registration No.: BE-MF-000001434

Products: Products of class IIa:

A010101 HYPODERMIC NEEDLES
A020199 SYRINGES - OTHERS
A010102 BUTTERFLY NEEDLES
U0601 UROLOGICAL GUIDEWIRES, HYDROPHILIC
G0399 DIGESTIVE ENDOSCOPY DEVICES – OTHER
C0504 ARTERIAL INTRODUCTION SETS
A010599 OPHTHALMOLOGY INJECTION NEEDLES AND KITS - OTHER

Authorised
representative(s): N/A

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 1142544-10

Effective date: 2023-06-20

Expiry date: 2026-12-31

Issue date: 2023-06-20



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
BS-MDR-091



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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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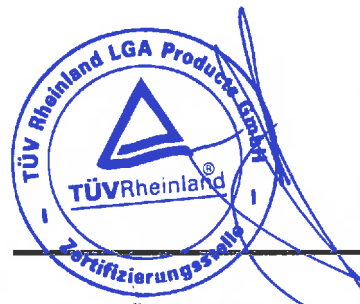
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Certificate history		
Revision:	Description:	Issue date:
1	First Issuance	2022-02-11
2	Update to include addition of 4 EMDN Codes to Products of Class IIa: U0601, G0399, C0504 and A010599 Note: Addition of U0601, G0399, C0504 codes per report no.: 3350367-530; and addition of A010599 code per report no.: 1142544-10	2023-06-20

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