EU Certificate

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

TÜVRheinland®

Registration No.:	HZ 2320977-1
Manufacturer:	**SP Medical A/S** Møllevej 1 4653 Karise Denmark
EUDAMED Single Registration No.:	DK-MF-000019782
Products:	Products of class I, sterile: A0599 - MECHANICAL INFUSION SYSTEMS, SINGLE-USE - OTHER The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions. Products of class III: C040101 - CORONARY ARTERY GUIDEWIRES CORONARY ARTERY DIAGNOSTIC GUIDEWIRES C040102 - CORONARY ARTERY GUIDEWIRES CORONARY ARTERY THERAPEUTIC GUIDEWIRES C040201 - PERIPHERAL VASCULAR GUIDEWIRES PERIPHERAL VASCULAR DIAGNOSTIC GUIDEWIRES C040202 - PERIPHERAL VASCULAR GUIDEWIRES PERIPHERAL VASCULAR THERAPEUTIC GUIDEWIRES
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.:	84956485-160
Effective date:	2022-03-29
Expiry date:	2026-11-18
Issue date:	2022-03-29

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

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜVRheinland®

Registration No.: HZ 2320977-1

Manufacturer: **SP Medical A/S**
Møllevej 1
4653 Karise
Denmark

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision.	2022-03-29

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TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

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