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 2320977-1
Manufacturer:	SP Medical A/S Møllevej 1 4653 Karise Denmark
EUDAMED Single Registration No.:	DK-FM-000019782
Products:	Products of class I, sterile: A0599 - MECHANICAL INFUSION SYSTEMS, SINGLE-USE - OTHER A0980 - ORGAN CONTAINERS - ACCESSORIES 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

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.:	84971274-30
Effective date:	2024-08-13
Expiry date:	2026-11-18
Issue date:	2024-08-13

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

This certificate can be validated on https://www.certipedia.com

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

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

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Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2320977-1
Manufacturer:	SP Medical A/S Møllevej 1 4653 Karise Denmark
EUDAMED Single Registration No.:	DK-FM-000019782
	Products of class IIa: C040201 - PERIPHERAL VASCULAR DIAGNOSTIC GUIDEWIRES C040202 - PERIPHERAL VASCULAR THERAPEUTIC GUIDEWIRES U0601 - UROLOGICAL GUIDEWIRES, HYDROPHILIC U0602 - UROLOGICAL GUIDEWIRES, NOT HYDROPHILIC G0399 - DIGESTIVE ENDOSCOPY DEVICES – OTHERS
Authorized representative(s):	Not applicable

Certificate history		
Revision:	Description:	Issue date:
1	Initial certification.	2022-03-29
1	Scope extension.	2022-07-07
2	Scope extension and change of existing EMDN code from K030202 to G0399.	2024-08-13

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