

# 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-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

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.: 84961872-50

Effective date: 2022-07-07

Expiry date: 2026-11-18

Issue date: 2022-07-07



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TÜV Rheinland LGA Products GmbH  
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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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Products of class IIa:  
C040201 - PERIPHERAL VASCULAR DIAGNOSTIC GUIDEWIRES  
C040202 - PERIPHERAL VASCULAR THERAPEUTIC GUIDEWIRES  
U0601 - UROLOGICAL GUIDEWIRES, HYDROPHILIC  
U0602 - UROLOGICAL GUIDEWIRES, NOT HYDROPHILIC  
K030202 - ARTHROSCOPY GUIDE WIRES, SINGLE-USE

Authorised representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision.	2022-03-29
2	Extension.	2022-07-07

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