EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/745 on Medical Devices,
Annex IX Chapter II, Section 4

TÜVRheinland®

Registration No.:	IZ 2320977-2
Manufacturer:	**SP Medical A/S** Møllevej 1 4653 Karise Denmark
EUDAMED Single Registration No.:	DK-MF-000019782
General product group name:	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
Models and types:	- Sub-types: Standard, Stiff - Tip subtype: Floppy, Soft, Standard - Variants: Straight, Angled, Double Ended, Reshapable
Basic UDI-DI:	5710086-GWPOLZ
Intended use:	General intravascular and coronary arterial use to aid in the selective placement of interventional devices during diagnostic and/or therapeutic procedures

The Notified Body hereby declares that the requirements of Annex IX, Chapter II, Section 4 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate is required before placing the listed products on the market.

Report No.:	84961872-50
Effective date:	2022-07-07
Expiry date:	2027-07-06
Issue date:	2022-07-07

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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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Registration No.: IZ 2320977-2

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

Product name: Poseidon Hydrophilic Nitinol Guide Wires

Authorised representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision.	2022-07-07

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