

EU Certificate

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



Registration No.: IZ 2320977-1

Manufacturer: **SP Medical A/S**
Møllevvej 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:
- Seldinger - Straight
- Seldinger - J-tip
- Seldinger - Double ended
- Seldinger Movable - Straight
- Seldinger Movable - J-tip

Basic UDI-DI: 5710086-GWACJU

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: 2027-03-28

Issue date: 2022-07-07



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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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Intended use: General intravascular and coronary arterial use to aid in the selective placement of interventional devices during diagnostic and/or therapeutic procedures.

Product name: Accoat Guide Wires

Authorised representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision.	2022-03-29
2	Correction of Basic UDI-DI.	2022-07-07

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