

# EU Certificate

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



Registration No.: IZ 2320977-3

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

EUDAMED Single  
Registration No.: DK-MF-000019782

General product group  
name: C040101 - CORONARY ARTERY DIAGNOSTIC GUIDEWIRES  
C040102 - CORONARY ARTERY THERAPEUTIC GUIDEWIRES  
MDN 1203 Non-active non-implantable guide catheters, balloon catheters,  
guidewires, introducers, filters, and related tools

Models and types: - Champion PTCA Guide Wire - CTO  
- Champion PTCA Guide Wire - CAR

Basic UDI-DI: 5710086-GWC2J2

Classification: III

Intended use: It is indicated for general use in the coronary vasculature to aid in the selective  
placement of interventional devices during diagnostic and/or therapeutic  
procedures.

Product name: Champion PTCA Guide Wire

Authorised  
representative(s): N/A

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.: 84952932-120

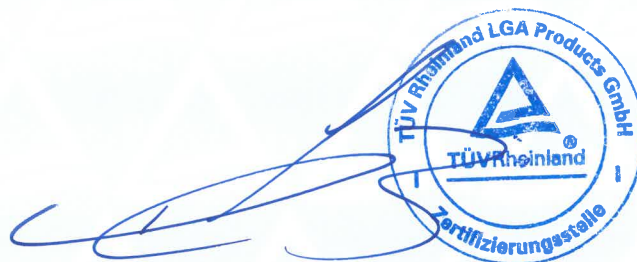
Effective date: 2023-02-07

Expiry date: 2028-02-06

Issue date: 2023-02-07



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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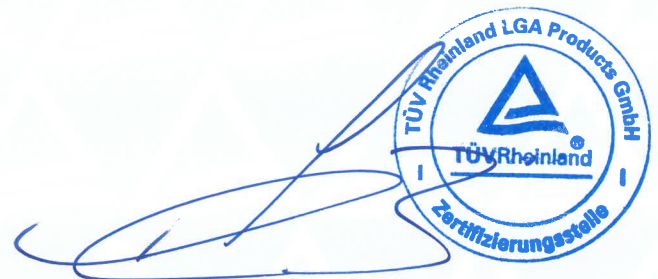
Certificate history		
Revision:	Description:	Issue date:
0	Initial	2023-02-07

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