ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 045257 0048 Rev. 00

Manufacturer:

Cook Incorporated
750 Daniels Way
Bloomington IN 47404
USA

SRN Manufacturer: US-MF-000003180

Authorized Representative:

Cook Medical Europe Ltd
O'Halloran Road, National Technology Park, V94N8X2 Limerick, IRELAND

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G12 045257 0048 Rev. 00

Report No.: 72179857

Valid from: 2022-06-23
Valid until: 2027-06-22

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-06-23

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G12 045257 0048 Rev. 00

Classification:	III
Device Group:	C0502 - CARDIOVASCULAR INTRODUCER SHEATHS, VALVED
Intended Purpose:	The intended purpose of these devices is to serve as a pathway for other devices to be inserted into the vascular system. The introducer is not intended to be placed in the coronary or neuro vasculature.
The validity of this certificate depends on conditions and/or is limited to the following:	-

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