



## EU Technical Documentation Assessment Certificate (MDR)

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

**No. G70 045257 0049 Rev. 00**

<b>Manufacturer:</b>	<b>Cook Incorporated</b> 750 Daniels Way Bloomington IN 47404 USA
<b>SRN Manufacturer:</b>	US-MF-000003180
<b>Authorized Representative:</b>	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 drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment 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:G70 045257 0049 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G70_045257_0049_Rev_00)

<b>Report No.:</b>	713252403
<b>Valid from:</b>	2022-06-23
<b>Valid until:</b>	2027-06-22

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2022-06-23



## EU Technical Documentation Assessment Certificate (MDR)

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

**No. G70 045257 0049 Rev. 00**

**Classification:** III  
**Device Group:** C0502 - CARDIOVASCULAR INTRODUCER SHEATHS, VALVED  
**Basic UDI-DI:** 0827002CINC050-032\_AHS

**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.

**Device(s):** Flexor® Tuohy-Borst Side-Arm Introducer

**The validity of this certificate depends on conditions and/or is limited to the following:** ./.

Model Name	Model Number
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-4.0-18/35-110-RB-SHTL-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-4.0-18/35-90-RB-SHTL-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-5.0-18/38-110-RB-SHTL-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-5.0-18/38-90-RB-SHTL
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-5.0-18/38-90-RB-SHTL-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle Select®)	KSAW-5.0-38-90-RB-SHTL-FLEX-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-6.0-38-110-RB-SHTL-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-6.0-38-80-RB-SHTL
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-6.0-38-80-RB-SHTL-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-6.0-38-90-RB-SHTL
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle Select®)	KSAW-6.0-38-90-RB-SHTL-FLEX-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-6.0-38-90-RB-SHTL-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-7.0-38-80-RB-SHTL
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-7.0-38-80-RB-SHTL-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-7.0-38-90-RB-SHTL
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-7.0-38-90-RB-SHTL-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-8.0-38-80-RB-SHTL-HC
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle®- SL)	KSAW-8.0-38-90-RB-SHTL-HC