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 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 014607 0248 Rev. 00

Manufacturer:

St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar CA 91342
USA

Authorized Representative:

St. Jude Medical Coordination Center BVBA
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem,
BELGIUM

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 014607 0248 Rev. 00

Report No.: 713198441

Valid from: 2021-05-14
Valid until: 2026-05-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-05-14

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. G70 014607 0248 Rev. 00

Classification:	III
Device Group:	C0503 - CARDIOVASCULAR INTRODUCING SHEATHS, PEEL-AWAY
Basic UDI-DI:	5415067ALP0001D6
Intended Purpose:	The CPS Catheter is intended to provide a transvenous conduit for navigation of the coronary venous system anatomy and delivery pathway during cardiac surgery procedures for contrast media, implantable left heart pacing leads, or other delivery tools.
Device(s):	CPS Direct™ PL Peelable Outer Guide Catheter 410210, 410211, 410212, 410213, 410214, 410215, 410216, 410217, 410218, 410219, 410220, 410221, 410222, 410223, 410224, 410225
Classification:	III
Device Group:	C0502 - CARDIOVASCULAR INTRODUCING SHEATHS, VALVULATED
Basic UDI-DI:	5415067ALP0001D6
Intended Purpose:	The CPS Catheter is intended to provide a transvenous conduit for navigation of the coronary venous system anatomy and delivery pathway during cardiac surgery procedures for contrast media, implantable left heart pacing leads, or other delivery tools.
Device(s):	CPS Aim™ SL Slittable Inner Catheter DS2N021-59, DS2N021-65, DS2N022-59, DS2N022-65, DS2N023-59, DS2N023-65, DS2N024-65, DS2N025-65 CPS Direct™ SL II Slittable Outer Guide Catheter DS2C001, DS2C002, DS2C003, DS2C004, DS2C005, DS2C006, DS2C011, DS2C012, DS2C013, DS2C014, DS2C015 CPS Aim™ Universal Slittable Inner Catheter DS2N026-59, DS2N026-65, DS2N027-59, DS2N027-65, DS2N028-59, DS2N028-65, DS2N029-65, DS2N030-65
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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