SLITTABLE OUTER GUIDE CATHETER

CPS Direct™ Universal 3D

Models DS2C029

Digitally signed by Ceaicovschi Tudor
Date: 2025.09.10 10:46:22 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Specifications

- The CPS Direct™ Universal slittable Outer Guide Catheters are designed to facilitate left heart lead delivery. They are compatible with other products in the Abbott CPS™ Cardiac Positioning System family — an inter-compatible system of tools designed to give you more control to efficiently and predictably deliver the left heart lead to your vein of first choice.
- Designed to provide reliable coronary sinus access:
  - Excellent torque transmission and soft tip are due to braid-reinforced, multi-durometer PEBAX‡ material design.
  - Unique SiteMark™ Markers provide 3-D fluoroscopic visibility to determine anterior/posterior location and verify torque transfer.
- Designed to reduce procedural steps during implant:
  - Slittable hub and integrated shaft provide smooth transition during slitting of the catheter.
  - U-channel valve bypass tool simplifies lead delivery.
  - Ergonomic slitter facilitates smooth slitting.
- Designed for removal:
  - Catheter design features Smooth-Slit™ Technology and an ergonomic slitter, which are designed to allow cutting, minimizing the risk of lead dislodgement upon catheter removal.

Physical Specifications

MODEL #	CURVE SHAPE	AVAILABLE LENGTH	OVERALL LENGTH	INNER DIAMETER	OUTER DIAMETER
DS2C029	3D	42 cm	45.7 cm	8.01 F (2.67 mm)	9.90 F (3.30 mm)
Material	Multi-durometer PEBAX‡ material reinforced with stainless steel braid wire for a kink-resistant catheter shaft and soft distal tip. Lubricious coating on inner and outer surfaces.				
Marker	Three gold marker bands and two tungsten stripes on distal tip.				

Accessories

INCLUDED
Dilator
2 Valve Bypass Tools

SEPERATELY AVAILABLE	MODEL NUMBER
CPS™ Universal Slitter	DS2A003
CPS Direct™ Valve Bypass Tool	410194

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner

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Abbott.com

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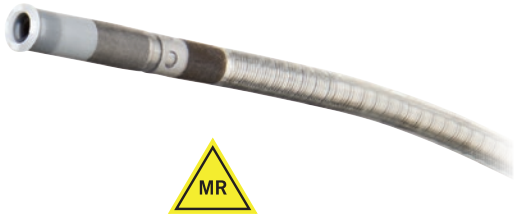
Tendril™ STS

Pacing Lead



Product Highlights - Pacing Leads

- The Tendril™ STS lead allows patients to undergo 1.5 T or 3 T MRI scans when used in conjunction with an MRI Ready device from Abbott*
- Soft silicone tip offers more compliance and less tip pressure at the lead tip-endocardium interface
- Small diameter lead offers improved ease of venous passage, reduced risk of venous thrombosis or rib-clavicle crush and ability to accommodate additional leads more easily
- Optim™ lead insulation — a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Titanium nitride (TiN) fractal coating on the tip and ring electrodes is designed to promote precise sensing and to provide improved contact with the myocardium
- Lubricious Fast-Pass™ coating facilitates lead insertion through the introducer and veins to ease implantation
- Fits through a 6 F introducer

Ordering Information

MODEL NUMBER	DESCRIPTION	INSULATION	FIXATION	MIN. INTRODUCER (F)	CONNECTOR	LENGTH (CM)
2088TC	Tendril™ STS Pacing Leads	Optim™	Ext/Ret helix	6	IS-1 bipolar	46**; 52**; 58**; 65; 100

*See MRI conditional parameters.
**Indicates lead lengths that are MRI conditional.

Indications: Tendril™ STS Lead is designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible device. Active leads such as the Tendril STS lead may be indicated for patients where permanent fixation of passive leads is suspected to be unstable.

In atrial applications, the use of screw-in leads such as Tendril STS lead may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: Tendril STS lead is contraindicated: in the presence of tricuspid atresia, for patients with mechanical tricuspid valves, in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Adverse Events: Potential complications associated with the use of Tendril STS lead are the same as with the use of other active fixation leads and include: cardiac tamponade, diaphragmatic stimulation, embolism, excessive bleeding, induced ventricular ectopy, infection, loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead, phrenic nerve stimulation, thrombosis. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and, rarely, death.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Tendril™ STS

Pacing Lead

Product Specifications

PHYSICAL SPECIFICATIONS

Models	2088TC
Minimum Introducer Size	6 F
Type of Lead	Active-fixation, steroid-eluting, endocardial, straight pacing lead
Lead Connector	IS-1 bipolar
Lead Lengths	46**; 52**; 58**; 65; 100 cm
Fixation Mechanism	Extendable/Retractable helix
Typical Number of Rotations for Helix Extension	6–11 (straight stylet)
Lead Body Diameter	1,9 mm (max)
Tip-to-Ring Spacing	10 mm
Lead Tip Electrode (Cathode)	Active Titanium-nitride-coated Pt/Ir helix (2,0 mm extension)
Tip Electrode Surface Area	6,9 mm^2
Ring Electrode (Anode)	Titanium-nitride-coated Pt/Ir
Ring Electrode Surface Area	16 mm^2
Mapping	Capable with Titanium-nitride-coated Pt/Ir helix
Steroid	< 1 mg dexamethasone sodium phosphate
Inner Conductor/Outer Conductor	MP35N™* coil
Inner Insulation	Silicone rubber
Outer Insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating

In-Pack	
Straight stylets	1 installed in lead, 1 straight
J-shaped stylets	1 J-shape
Helix extension/retraction clip-on tools	2 clip-on tools

Accessory Kits Available Separately	Model Number	Compatible Lenghts	Description
Stylet Kit	DSO6003 with appropriate length designation	46; 52; 58; 65; 100 cm	1 clip-on tool, 1 J-shaped soft, 1 x-soft, 1 soft, 1 firm, 1 x-firm
	DSO6001 with appropriate length designation	46; 52; 58; 65; 100 cm	1 clip-on tool, 2 straight stylets 1 J-shaped
Locator™ Plus Deflectable Stylet	1281 with appropriate length designation	46; 52; 58 cm	Disposable implant tool to facilitate precise lead positioning and manipulation with one hand
	1292 with appropriate length designation	46; 52; 58 cm	

MRI Conditional Parameters

MRI scan parameters vary depending on the MRI Ready device used. Consult the MRI Ready System Manual for specific product combinations and associated MRI scan parameters.

MP35N is a trademark of SPS Technologies, LLC

MR

*See MRI conditional parameters.

**Indicates lead lengths that are MRI conditional.

Customer Support: 46-8-474-4756

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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 0243 Rev. 01

Manufacturer:

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

SRN Manufacturer: US-MF-000010382

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 0243 Rev. 01

Report No.: 713229674

Preceding Certificate No.: G70 014607 0243 Rev. 00

Valid from: 2021-11-10
Valid until: 2026-05-04

Date of Initial Issuance: 2021-05-05

Issue date: 2021-11-10

Christoph Dicks
Head of Certification/Notified Body

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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 0243 Rev. 01

Classification:	III
Device Group:	C0502 - CARDIOVASCULAR INTRODUCING SHEATHS, VALVULATED
Basic UDI-DI:	5415067ALP0001D6
Intended Purpose:	The CPS Direct™ Universal Slittable Outer Guide 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 such as guidewires and inner catheters.
Device(s):	CPS Direct™ Universal Slittable Outer Guide Catheter For device variants/models and parameters please see model list at the end of this certificate
The validity of this certificate depends on conditions and/or is limited to the following:	n/a

Revision History:

Rev.	Dated	Report
00	2021-05-05	713183532

DS2C018, CPS Direct™ Universal Slittable Outer Guide Catheter, Straight, 47 cm
DS2C019, CPS Direct™ Universal Slittable Outer Guide Catheter, 115°, 47 cm
DS2C020, CPS Direct™ Universal Slittable Outer Guide Catheter 135°, 47 cm
DS2C021, CPS Direct™ Universal Slittable Outer Guide Catheter, Wide, 47 cm
DS2C022, CPS Direct™ Universal Slittable Outer Guide Catheter, X-Wide, 47 cm
DS2C023, CPS Direct™ Universal Slittable Outer Guide Catheter, Right Sided, 47 cm
DS2C025, CPS Direct™ Universal Slittable Outer Guide Catheter, Straight, 54 cm
DS2C026, CPS Direct™ Universal Slittable Outer Guide Catheter, 115°, 54cm
DS2C027, CPS Direct™ Universal Slittable Outer Guide Catheter, 135°, 54 cm
DS2C028, CPS Direct™ Universal Slittable Outer Guide Catheter, Wide, 54 cm
DS2C029, CPS Direct™ Universal Slittable Outer Guide Catheter, X-Wide, 54 cm

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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 014607 0255 Rev. 06

Manufacturer:

Abbott Medical
15900 Valley View Court
Sylmar CA 91342
USA

SRN Manufacturer - US-MF-000010383

Authorized Representative:

Abbott Medical
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 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 014607 0255 Rev. 06

Report No.: 713312217

Preceding Certificate No.: G12 014607 0255 Rev. 05

Valid from: 2023-11-22
Valid until: 2027-08-14

Date of Initial Issuance: 2022-08-15

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-11-22

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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 014607 0255 Rev. 06

Classification:	Class III
Device Group:	J01900282 - IMPLANTABLE CARDIAC DEVICES PROGRAMMERS - SOFTWARE ACCESSORY
Intended Purpose:	-

Classification:	Class III
Device Group:	J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS
Intended Purpose:	-

Classification:	Class III
Device Group:	J010502 - IMPLANTABLE DUAL CHAMBER DEFIBRILLATORS
Intended Purpose:	-

Classification:	Class III
Device Group:	J010503 - IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS
Intended Purpose:	-

Classification:	Class III
Device Group:	J010201 - IMPLANTABLE DIAGNOSTIC ARRHYTHMIAS RECORDING CARDIAC DEVICES
Intended Purpose:	-

Classification:	Class III
Device Group:	C0502 - CARDIOVASCULAR INTRODUCER SHEATHS, VALVED
Intended Purpose:	-

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Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
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No. G12 014607 0255 Rev. 06

Classification:	Class III
Device Group:	C0503 - CARDIOVASCULAR INTRODUCER SHEATHS, PEEL-AWAY
Intended Purpose:	-

Classification:	Class III
Device Group:	C010299 - CENTRAL VENOUS CATHETERS - OTHER
Intended Purpose:	-

Classification:	Class III
Device Group:	J0190010102 - ENDOCARDIAL ATRIAL AND VENTRICULAR LEADS, BIPOLAR (WITH ACTIVE OR PASSIVE FIXATION)
Intended Purpose:	-

Classification:	Class III
Device Group:	J0190010103 - LEFT VENTRICULAR LEADS WITH CORONARY SINUS CANNULATION SYSTEM (TRIPLE CHAMBER P.M.)
Intended Purpose:	-

Classification:	Class III
Device Group:	J01900180 - PERMANENT CARDIAC LEADS - ACCESSORIES
Intended Purpose:	-

Classification:	Class III
Device Group:	J010105 - IMPLANTABLE PACEMAKERS WITH INCORPORATED ELECTRODES (LEADLESS)
Intended Purpose:	-

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No. G12 014607 0255 Rev. 06

Classification:	Class III
Device Group:	J01900280 - IMPLANTABLE CARDIAC DEVICES PROGRAMMERS - HARDWARE ACCESSORY
Intended Purpose:	-
Classification:	Class III
Device Group:	J01010101 - IMPLANTABLE SINGLE CHAMBER PACEMAKERS (SC)
Intended Purpose:	-
Classification:	Class III
Device Group:	J01010301 - IMPLANTABLE DUAL CHAMBER PACEMAKERS (DC)
Intended Purpose:	-
Classification:	Class III
Device Group:	J01010401 - IMPLANTABLE TRIPLE CHAMBER PACEMAKERS FOR CARDIAC RESYNCHRONIZATION (TR)
Intended Purpose:	-
Classification:	Class III
Device Group:	J010782 - ACTIVE IMPLANTABLE CARDIAC DEVICES REMOTE MONITORING SYSTEMS - SOFTWARE ACCESSORIES
Intended Purpose:	-
Classification:	Class III
Device Group:	J010792 - ACTIVE IMPLANTABLE CARDIAC DEVICES REMOTE MONITORING SYSTEMS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	-

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No. G12 014607 0255 Rev. 06

Classification:	Class III
Device Group:	J010799 - ACTIVE IMPLANTABLE CARDIAC DEVICES REMOTE MONITORING SYSTEMS - OTHER
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2022-08-15	713262605	-
01	2022-11-29	713224043	-
02	2023-05-10	713237689_CN_G12	Supplemented: Device(s)/group of device(s) added
03	2023-07-21	713303375	Supplemented: Device(s)/group of device(s) added
04	2023-07-27	713304712	Supplemented: Device(s)/group of device(s) added
05	2023-09-21	713307778	Supplemented: Device(s)/group of device(s) added
06	2023-11-22	713312217	Supplemented: Device(s)/group of device(s) added

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

No. G70 014607 0262 Rev. 02

Manufacturer:

Abbott Medical
15900 Valley View Court
Sylmar CA 91342
USA

SRN Manufacturer - US-MF-000010383

Authorized Representative:

Abbott Medical
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, BELGIUM

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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 0262 Rev. 02

Report No.: 713251685

Preceding Certificate No.: G70 014607 0262 Rev. 01

Valid from: 2024-01-17
Valid until: 2028-06-04

Date of Initial Issuance: 2023-06-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-01-17

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No. G70 014607 0262 Rev. 02

Classification:	Class III
Device Group:	J01900180 - PERMANENT CARDIAC LEADS - ACCESSORIES
Basic UDI-DI:	5415067ALD00079E
Intended Purpose:	The suture sleeve is intended to protect the lead from damage when it is secured to the venous entry site.
Device(s):	Suture Sleeve DS2A088

Classification:	Class III
Device Group:	J0190010102 - ENDOCARDIAL ATRIAL AND VENTRICULAR LEADS, BIPOLAR (WITH ACTIVE OR PASSIVE FIXATION)
Basic UDI-DI:	5415067LVL0001MP
Intended Purpose:	The IsoFlex™ leads are bipolar, steroid-eluting, passive-fixation implantable leads intended for use with an implantable pulse generator to provide long-term cardiac pacing and sensing in either the right atrium or the right ventricle.
Device(s):	IsoFlex™ 1944 46cm IsoFlex™ 1944 52cm IsoFlex™ 1948 52cm IsoFlex™ 1948 58cm

Classification:	Class III
Device Group:	J0190010102 - ENDOCARDIAL ATRIAL AND VENTRICULAR LEADS, BIPOLAR (WITH ACTIVE OR PASSIVE FIXATION)
Basic UDI-DI:	5415067LVL0001MP
Intended Purpose:	The Tendril™ STS 2088TC leads are bipolar, steroid eluting, active fixation implantable leads intended for use with an implantable pulse generator to provide long-term cardiac pacing and sensing in either the right atrium or right ventricle.
Device(s):	Tendril™ STS 2088TC 46cm, Tendril™ STS 2088TC 52cm, Tendril™ STS 2088TC 58cm, Tendril™ STS 2088TC 65cm, Tendril™ STS 2088TC 100cm

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(Implantable Class IIb Devices and Class III Devices)

No. G70 014607 0262 Rev. 02

Classification:	Class III
Device Group:	J0190010103 - LEFT VENTRICULAR LEADS WITH CORONARY SINUS CANNULATION SYSTEM (TRIPLE CHAMBER P.M.)
Basic UDI-DI:	5415067LVL0002MR
Intended Purpose:	The Quartet™ leads are quadripolar, steroid-eluting, passive-fixation implantable leads intended for use with cardiac resynchronization therapy (CRT) devices to provide long-term cardiac pacing and sensing in the left ventricle.
Device(s):	Quartet™ 1456Q 75cm Quartet™ 1456Q 86cm Quartet™ 1457Q 75cm Quartet™ 1457Q 86cm Quartet™ 1458Q 75cm Quartet™ 1458Q 86cm Quartet™ 1458Q 92cm Quartet™ 1458QL 75cm Quartet™ 1458QL 86cm

Classification:	Class III
Device Group:	J0190010103 - LEFT VENTRICULAR LEADS WITH CORONARY SINUS CANNULATION SYSTEM (TRIPLE CHAMBER P.M.)
Basic UDI-DI:	5415067LVL0002MR
Intended Purpose:	The QuickFlex™ µ leads are bipolar, steroid-eluting, passive-fixation implantable leads intended for use with cardiac resynchronization therapy (CRT) devices to provide long-term cardiac pacing and sensing in the left ventricle.
Device(s):	QuickFlex™ µ 1258T 75cm QuickFlex™ µ 1258T 86cm QuickFlex™ µ 1258T 92cm

Classification:	Class III
Device Group:	J0190010102 - ENDOCARDIAL ATRIAL AND VENTRICULAR LEADS, BIPOLAR (WITH ACTIVE OR PASSIVE FIXATION)
Basic UDI-DI:	5415067LVL0001MP
Intended Purpose:	The OptiSense™ leads are bipolar, steroid-eluting, active fixation implantable leads intended for use with an implantable pulse generator to provide long-term cardiac pacing and sensing in the right atrium.
Device(s):	OptiSense™ 1999 46cm OptiSense™ 1999 52cm

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TÜV SÜD 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 0262 Rev. 02

Classification:	Class III
Device Group:	J01900180 - PERMANENT CARDIAC LEADS - ACCESSORIES
Basic UDI-DI:	5415067ALD00089G
Intended Purpose:	Aid in maneuvering the lead through the venous system Torque Tool: To provide adequate grip and control of the guidewire for lead delivery.
Device(s):	Guidewire/Torque Tool Accessory Kit 4078G (180)

Classification:	Class III
Device Group:	J01900180 - PERMANENT CARDIAC LEADS - ACCESSORIES
Basic UDI-DI:	5415067ALD00099J
Intended Purpose:	Stiffen and support the lead to facilitate placement.
Device(s):	Stylet Kit DS06001 (Length 46) Stylet Kit DS06001 (Length 52) Ball-Tipped Stylet Kit 4078S (75/15) Ball-Tipped Stylet Kit 4078S (86/15) Ball-Tipped Stylet Kit 4078S (86/5) Stylet Assy 4078S (92/15)

Classification:	Class III
Device Group:	J01900180 - PERMANENT CARDIAC LEADS - ACCESSORIES
Basic UDI-DI:	5415067ALD001093
Intended Purpose:	Aid in insertion of the guidewire into introducer for lead implantation. Torque Tool: To provide adequate grip and control of the guidewire for lead delivery.
Device(s):	Torque Tool / Tip Introducer 4071

Classification:	Class III
Device Group:	J01900180 - PERMANENT CARDIAC LEADS - ACCESSORIES
Basic UDI-DI:	5415067ALD001195
Intended Purpose:	Extend and retract the helix of an active fixation lead.
Device(s):	Helix Locking Tool A001HELX

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TÜV SÜD 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 0262 Rev. 02

Classification:	Class III
Device Group:	J0190010102 - ENDOCARDIAL ATRIAL AND VENTRICULAR LEADS, BIPOLAR (WITH ACTIVE OR PASSIVE FIXATION)
Basic UDI-DI:	5415067LVL0001MP
Intended Purpose:	UltiPace™ leads are bipolar, steroid eluting, active fixation implantable leads intended for use with an implantable pulse generator to provide long-term cardiac pacing and sensing in either the right atrium or right ventricle.
Device(s):	UltiPace™ LPA1231 46cm UltiPace™ LPA1231 52cm UltiPace™ LPA1231 58cm UltiPace™ LPA1231 65cm

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

Revision History:

Rev.	Dated	Report	Description
00	2023-06-05	713224005	Initial issuance
01	2023-11-30	713280529	Supplemented: Device(s)/group of device(s) added
02	2024-01-17	713251685	Supplemented: Device(s)/group of device(s) added

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TÜV®

St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar, California 91342 USA
Tel: +1 818 362 6822

0047281 Rev. B [English]

MDR Declaration of Conformity

Manufacturer:	St. Jude Medical Cardiac Rhythm Management Division
Manufacturer SRN:	US-MF-000010382
Address:	15900 Valley View Court Sylmar, California 91342 USA
Manufacturing Site(s):	St. Jude Medical Cardiac Rhythm Management Division 15900 Valley View Court Sylmar, California 91342 USA
European Authorized Representative:	SJM Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
European Authorized Representative SRN:	BE-AR-000008417

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Type:	Cardiovascular delivery catheter
Product Trade Name(s):	CPS Direct™ Universal Slittable Outer Guide Catheter
Model Number(s):	DS2C018, DS2C019, DS2C020, DS2C021, DS2C022, DS2C023, DS2C025, DS2C026, DS2C027, DS2C028, DS2C029
Intended Purpose:	The CPS Direct™ Universal Slittable Outer 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 such as guidewires and inner catheters.
Risk Classification:	Class III

Signature: CANANCX Digitally signed by CANANCX Date: 2021.12.01 10:12:39 -08'00' Colleen Canan Director Regulatory Affairs	_December 1, 2021_ Issue Date On behalf of St. Jude Medical Cardiac Rhythm Management Division, signed at Sylmar, CA

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0047281 Rev. B [English]

MDR Declaration of Conformity

Classification Rationale:	EU MDR 2017/745, Annex VIII, Chapter III, Rule 6, Bullet 3
EMDN Code(s):	C0502 – Cardiovascular Introducing Sheaths, Valvulated
Basic UDI-DI:	5415067ALP0001D6

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Medical Device Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1

Common Specifications Applied:	Not Applicable. No common specifications are available for this type of device.
STED #	62360
Notified Body:	TÜV SÜD Product Services GmbH Ridlerstraße 65 80339 München/Munich Deutschland/Germany ID Number: 0123
Supporting Certificate(s):	EU Technical Documentation Assessment Certificate (MDR) No: G70 014607 0243 Rev. 01 Expiration Date: May 4, 2026 EU Quality Management System Certificate (MDR) No: G12 014607 0244 Rev. 00 Expiration Date: April 6, 2026
Original CE Mark Date:	May 13, 2013 (AIMDD)
Conformity Assessment:	EU MDR 2017/745, Annex IX
Device Photograph:	Not Applicable. Identification and traceability achieved through Model Numbers listed above.

REPUBLICA MOLDOVA, or. STRĂȘENI, «SANTE DISTRIBUȚIE» S.R.L., IDNO 1014600040477, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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0047281 Rev. B [English]

MDR Declaration of Conformity

The products in the below Declaration of Conformity Product List are approved under EU Technical Documentation Assessment Certificate (MDR) No. G70 014607 0243 Rev. 01

Declaration of Conformity Product List

Model No.	Description
DS2C018	CPS Direct™ Universal Slittable Outer Guide Catheter
DS2C019	CPS Direct™ Universal Slittable Outer Guide Catheter
DS2C020	CPS Direct™ Universal Slittable Outer Guide Catheter
DS2C021	CPS Direct™ Universal Slittable Outer Guide Catheter
DS2C022	CPS Direct™ Universal Slittable Outer Guide Catheter
DS2C023	CPS Direct™ Universal Slittable Outer Guide Catheter
DS2C025	CPS Direct™ Universal Slittable Outer Guide Catheter
DS2C026	CPS Direct™ Universal Slittable Outer Guide Catheter
DS2C027	CPS Direct™ Universal Slittable Outer Guide Catheter
DS2C028	CPS Direct™ Universal Slittable Outer Guide Catheter
DS2C029	CPS Direct™ Universal Slittable Outer Guide Catheter

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Fax: 1 818 364 5814

00144886 Rev. F

Declaration of Conformity

Manufacturer:	Abbott Medical
Manufacturer SRN:	US-MF-000010383
Address:	15900 Valley View Court Sylmar, CA 91342 United States of America
Manufacturing Site(s):	Abbott Medical 15900 Valley View Court Sylmar, CA 91342 United States of America Abbott Medical Lot A Interior - #2 Rd Km. 67.5 Santana Industrial Park, Arecibo PR, 00612 United States of America Abbott Medical Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone 11900 Penang Malaysia
European Authorized Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
European Authorized Representative SRN:	BE-AR-000008744

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Trade Name(s):	See attached Product List
Model Number(s):	See attached Product List

Signature: C.Canan Colleen Canan Divisional Vice President Regulatory Affairs	March 13, 2024 Issue Date On behalf of Abbott Medical, signed at Sylmar, CA, USA

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MDR Declaration of Conformity

Intended Purpose:	Tendril™ STS	The Tendril™ STS 2088TC leads are bipolar, steroid eluting, active fixation implantable leads intended for use with an implantable pulse generator to provide long-term cardiac pacing and sensing in either the right atrium or right ventricle.
	IsoFlex™	The IsoFlex™ leads are bipolar, steroid-eluting, passive-fixation implantable leads intended for use with an implantable pulse generator to provide long-term cardiac pacing and sensing in either the right atrium or the right ventricle.
	OptiSense™	The OptiSense™ leads are bipolar, steroid-eluting, active fixation implantable leads intended for use with an implantable pulse generator to provide long-term cardiac pacing and sensing in the right atrium.
	QuickFlex™ µ	The QuickFlex™ µ leads are bipolar, steroid-eluting, passive-fixation implantable leads intended for use with cardiac resynchronization therapy (CRT) devices to provide long-term cardiac pacing and sensing in the left ventricle.
	Quartet™	The Quartet™ leads are quadripolar, steroid-eluting, passive-fixation implantable leads intended for use with cardiac resynchronization therapy (CRT) devices to provide long-term cardiac pacing and sensing in the left ventricle.
	Suture Sleeve	The suture sleeve is intended to protect the lead from damage when it is secured to the venous entry site.
	Helix Locking Tool	Extend and retract the helix of an active fixation lead.
	UltiPace™	UltiPace™ leads are bipolar, steroid eluting, active fixation implantation leads intended for use with an implantable pulse generator to provide long-term cardiac pacing and sensing in either the right atrium or right ventricle.

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MDR Declaration of Conformity

Risk Classification:	Class III as per EU MDR 2017/745, Annex VIII
Risk Classification Rationale:	EU MDR 2017/745, Annex VIII, Rule 8_6
EMDN Code(s):	See attached Product List
GMDN Code:	See attached Product List
Basic UDI-DI:	See attached Product List

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1

Common Specifications Applied:	Not Applicable. No common specifications are available for this type of device
Notified Body:	TÜV SÜD Product Services GmbH Ridlerstraße 65 80339 Munich, Germany ID Number: 0123
Supporting Certificate(s):	Technical Documentation Assessment Certificate: G70 014607 0262 Rev.02 Expiration Date: 2028-06-04 EU Quality Management System Certificate: G12 014607 0255 Rev. 06 Expiration Date: 2027-08-14
Original CE Mark Date:	See attached Product List
Conformity Assessment:	EU MDR 2017/745, Annex IX

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00144886 Rev. F

MDR Declaration of Conformity

The products in the attached Declaration of Conformity Product List are approved under EC Certificate G70 014607 0262 Rev.02.

Declaration of Conformity Product List

Product Trade Name	Model No.	Lead Length (cm)	Variant	Original CE Mark Date	EMDN Code	GMDN Code	Basic UDI-DI
Tendril™ STS	2088TC	46, 52, 58	MR Conditional	February 2, 2015	J0190010102	35223	5415067LVL0001MP
		65, 100	-	October 6, 2011			
IsoFlex™	1944	46, 52	MR Conditional	February 2, 2015			
	1948	52, 58	MR Conditional	February 2, 2015			
OptiSense™	1999	46, 52	-	April 29, 2008			
QuickFlex™ μ	1258T	75, 86, 92	-	September 29, 2008	J0190010103	35223	5415067LVL0002MR
Quartet™	1456Q	75	-	December 18, 2015			
		86	MR Conditional	December 18, 2015			
	1457Q	75	-	December 18, 2015			
		86	MR Conditional	December 18, 2015			
	1458QL	75	-	December 18, 2015			
		86	MR Conditional	December 18, 2015			
	1458Q	75	-	December 18, 2015			
		86	MR Conditional	December 18, 2015			
		92	-	September 30, 2009			
Suture Sleeve	DS2A088	-	-	June 6, 2023	J01900180	46225	5415067ALD00079E
Helix Locking Tool	A001HELX	-	-	November 30, 2023	J01900180	46455	5415067ALD001195
UltiPace™	LPA1231	46, 52, 58, 65 cm	MR Conditional	January 17, 2024	J0190010102	35223	5415067LVL0001MP

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