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

0047786 Rev. A [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

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

Product Type:	Cardiovascular delivery catheter accessories
Product Trade Name(s):	• CPS Direct™ Valve Bypass Tool • CPS Direct™ PL Valve Bypass Tool • CPS Aim™ SL Valve Bypass Tool • CPS™ Universal Slitter
Model Number(s):	

Model Number	Device Name
DS2A004	CPS Direct™ Valve Bypass Tool
410194	CPS Direct™ PL Valve Bypass Tool
DS2A002	CPS Aim™ SL Valve Bypass Tool
DS2A003	CPS™ Universal Slitter

Intended Purpose:	The CPS Universal Slitter is intended to slit the catheter after delivery of the left ventricular pacing lead.

Signature: CCanan Colleen Canan Director Regulatory Affairs	27-JULY-2021 Issue Date On behalf of St. Jude Medical Cardiac Rhythm Management Division, signed at Sylmar, CA

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	The CPS Valve Bypass Tool is intended to enable the entry of devices through the hemostasis valve.
Risk Classification:	Class I
Classification Rationale:	EU MDR 2017/745, Annex VIII, Chapter III, Rule 1
EMDN Code(s):	C0580 – Cardiovascular introducing sheaths - accessories
Basic UDI-DI:	CPS Valve Bypass Tools: 5415067ALP0002D8 CPS Universal Slitter: 5415067ALP0003DA

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 #	48700
Notified Body:	TÜV SÜD Product Services GmbH Ridlerstraße 65 80339 München/Munich Deutschland/Germany ID Number: 0123
Supporting Certificate(s):	EU Quality Management System Certificate (MDR) No: G11 014607 0245 Rev. 00 Expiration Date: April 6, 2026
Original CE Mark Date:	Model Number: Original CE Mark Date (AIMDD) DS2A004: September 11, 2009 410194: June 2, 2006 DS2A002: February 22, 2008 DS2A003: September 11, 2009
Conformity Assessment:	EU MDR 2017/745, Annex IX (excluding Chapter II)

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Device Photograph:	Not Applicable. Identification and traceability achieved through Model Numbers listed above.

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The products in the below Declaration of Conformity Product List are product types covered under EU Quality Management System Certificate (MDR) No: G11 014607 0245 Rev. 00

Declaration of Conformity Product List

Model No.	Description
DS2A004	CPS Direct™ Valve Bypass Tool
410194	CPS Direct™ PL Valve Bypass Tool
DS2A002	CPS Aim™ SL Valve Bypass Tool
DS2A003	CPS™ Universal Slitter

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