

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
Product Trade Name(s):	<ul style="list-style-type: none"> • CPS Direct™ PL Slittable Outer Guide Catheter • CPS Direct™ SL II Slittable Outer Guide Catheter • CPS Aim™ SL Slittable Inner Catheter • CPS Aim™ Universal Slittable Inner Catheter

Signature:  <hr/> Colleen Canan Director Regulatory Affairs	<div style="text-align: center;"> 27-JULY-2021 <hr/> Issue Date </div> <p>On behalf of St. Jude Medical Cardiac Rhythm Management Division, signed at Sylmar, CA</p>
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Model Number(s):	Device Name	Model Numbers
	CPS Direct™ PL Peelable Outer Guide Catheter	410210, 410211, 410212, 410213, 410214, 410215, 410216, 410217, 410218, 410219, 410220, 410221, 410222, 410223, 410224, 410225
	CPS Direct™ SL II Slittable Outer Guide Catheter	DS2C001, DS2C002, DS2C003, DS2C004, DS2C005, DS2C006, DS2C011, DS2C012, DS2C013, DS2C014, DS2C015
	CPS Aim™ SL Slittable Inner Catheter	DS2N021-59, DS2N021-65, DS2N022-59, DS2N022-65, DS2N023-59, DS2N023-65, DS2N024-65, DS2N025-65
	CPS Aim™ Universal Slittable Inner Catheter	DS2N026-59, DS2N026-65, DS2N027-59, DS2N027-65, DS2N028-59, DS2N028-65, DS2N029-65, DS2N030-65
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.	
Risk Classification:	Class III	
Classification Rationale:	EU MDR 2017/745, Annex VIII, Chapter III, Rule 6, Bullet 3	
EMDN Code(s):	Device Name	EMDN Code
	CPS Direct™ PL Peelable Outer Guide Catheter	C0503 – Cardiovascular Introducing Sheaths, Peelable
	CPS Direct™ SL II Slittable Outer Guide Catheter	C0502 – Cardiovascular Introducing Sheaths, Valvulated
	CPS Aim™ SL Slittable Inner Catheter	C0502 – Cardiovascular Introducing Sheaths, Valvulated
	CPS Aim™ Universal Slittable Inner Catheter	C0502 – Cardiovascular Introducing Sheaths, Valvulated
Basic UDI-DI:	5415067ALP0001D6	

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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 #	90612379	
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 0248 Rev. 00 Expiration Date: May 13, 2026 EU Quality Management System Certificate (MDR) No: G12 014607 0244 Rev. 00 Expiration Date: April 6, 2026	
Original CE Mark Date:	Device Name	Original CE Mark Date (AIMDD)
	CPS Direct™ PL Peelable Outer Guide Catheter	June 2, 2006
	CPS Direct™ SL II Slittable Outer Guide Catheter	September 11, 2009
	CPS Aim™ SL Slittable Inner Catheter	September 10, 2009
	CPS Aim™ Universal Slittable Inner Catheter	May 13, 2013
Conformity Assessment:	EU MDR 2017/745, Annex IX	
Device Photograph:	Not Applicable. Identification and traceability achieved through Model Numbers listed above.	

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 0248 Rev. 00

Declaration of Conformity Product List

Model No.	Description
410210	CPS Direct™ PL Peelable Outer Guide Catheter
410211	CPS Direct™ PL Peelable Outer Guide Catheter
410212	CPS Direct™ PL Peelable Outer Guide Catheter
410213	CPS Direct™ PL Peelable Outer Guide Catheter
410214	CPS Direct™ PL Peelable Outer Guide Catheter
410215	CPS Direct™ PL Peelable Outer Guide Catheter
410216	CPS Direct™ PL Peelable Outer Guide Catheter
410224	CPS Direct™ PL Peelable Outer Guide Catheter
410217	CPS Direct™ PL Peelable Outer Guide Catheter
410218	CPS Direct™ PL Peelable Outer Guide Catheter
410219	CPS Direct™ PL Peelable Outer Guide Catheter
410220	CPS Direct™ PL Peelable Outer Guide Catheter
410221	CPS Direct™ PL Peelable Outer Guide Catheter
410222	CPS Direct™ PL Peelable Outer Guide Catheter
410223	CPS Direct™ PL Peelable Outer Guide Catheter
410225	CPS Direct™ PL Peelable Outer Guide Catheter
DS2C001	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C002	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C003	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C004	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C005	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C006	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C011	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C012	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C013	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C014	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2C015	CPS Direct™ SL II Slittable Outer Guide Catheter
DS2N021-59	CPS Aim™ SL Slittable Inner Catheter
DS2N021-65	CPS Aim™ SL Slittable Inner Catheter
DS2N022-59	CPS Aim™ SL Slittable Inner Catheter
DS2N022-65	CPS Aim™ SL Slittable Inner Catheter
DS2N023-59	CPS Aim™ SL Slittable Inner Catheter
DS2N023-65	CPS Aim™ SL Slittable Inner Catheter
DS2N024-65	CPS Aim™ SL Slittable Inner Catheter
DS2N025-65	CPS Aim™ SL Slittable Inner Catheter
DS2N026-59	CPS Aim™ Universal Slittable Inner Catheter
DS2N026-65	CPS Aim™ Universal Slittable Inner Catheter
DS2N027-59	CPS Aim™ Universal Slittable Inner Catheter
DS2N027-65	CPS Aim™ Universal Slittable Inner Catheter

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Model No.	Description
DS2N028-59	CPS Aim™ Universal Slittable Inner Catheter
DS2N028-65	CPS Aim™ Universal Slittable Inner Catheter
DS2N029-65	CPS Aim™ Universal Slittable Inner Catheter
DS2N030-65	CPS Aim™ Universal Slittable Inner Catheter