

	Title: EU MDR Declaration of Conformity (MDR)	Page No. 1 of 2
	DoC Document No. PIV-STED-008-DOC	Revision No: C

EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton Dickinson Infusion Therapy Systems Inc., 9450 South State Street, Sandy, Utah 84070, USA
Manufacturer SRN:	US-MF-000017719
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda, Co. Louth A92 YW26, Ireland
Authorised Representative SRN:	IE-AR-000007610
Product:	BD® Arterial Cannula
Basic UDI-DI:	038290GFYRCXIMDS
Risk Class and Rule:	Class IIa, Annex VIII, Rule 7
Intended Purpose	The BD® Arterial Cannula Product is intended for use only with: • Arterial pressure monitoring • Serial arterial blood gas determinations
Notified Body:	BSI Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797
We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s): • Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices	

Conformity Assessment Route:

☒ ANNEX IX Chapter I and III – Quality management System	EC CERTIFICATE No.: MDR 731353
☐ ANNEX IX Chapter II - Technical Documentation	EC CERTIFICATE No.:
☐ ANNEX X Type Examination	EC CERTIFICATE No.:
☐ ANNEX XI Part A Production Quality Assurance	EC CERTIFICATE No.:
☐ ANNEX XI Part B Product Verification	EC CERTIFICATE No.:
☐ ANNEX II & III Technical Documentation	N/A

	Title: EU MDR Declaration of Conformity (MDR)	Page No. 2 of 2
	DoC Document No. PIV-STED-008-DOC	Revision No: C

Common Specifications (CS):

Number: <Version/Year>	Title:	Full or Partial Application: <Justification>
N/A	N/A	N/A

Devices Covered by this DoC:

SKU#	Device Name	Device Class
682245	BD® Arterial Cannula	Class IIa

Authorised Signatory:	
Name & Title:	Christopher Rogers, VP Regulatory Affairs
On behalf of:	Becton Dickinson Infusion Therapy Systems Inc.
Place of Issue:	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah 84070 USA
Date of Issue:	2025-11-10
Signature:	Signed by:   Signer Name: Christopher Rogers Signing Reason: I approve this document Signing Time: 13-Nov-2025 7:05:27 AM PST 36D6BDC7D93A4EDD8A95BEA0996E41F8

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Original Release
B	Correct conformity assessment route (removing MDR certificate and unselecting Annex IX Chapter II). Remove references to Regulation (EU) 207/2012 on electronic instructions for use of medical devices
C	STED Periodic Review (2025): Updated to new STED Template GFM-10128EE. No changes to the content of DoC.

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