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	DoC Document No. PIV-STED-001-DOC	Revision No: E

Template GFM-10128EE

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:	Nexiva™ Diffusics™ Closed IV Catheter System
Basic UDI-DI:	038290KJKZSYMBJP
Risk Class and Rule:	Class IIa, Annex VIII, Rule 7
Intended Purpose	BD Nexiva™ Diffusics™ Closed IV Catheter System is intended to be inserted into a patient's peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. This device may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. This device is suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa) when access ports not suitable for use with power injectors are removed.
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.:

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☐ ANNEX II & III Technical Documentation	N/A
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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
383691	BD Nexiva™ Diffusics™ Closed IV Catheter System 24 GA 0.75 IN	Class IIa
383692	BD Nexiva™ Diffusics™ Closed IV Catheter System 22 GA 1.00 IN	Class IIa
383693	BD Nexiva™ Diffusics™ Closed IV Catheter System 20 GA 1.00 IN	Class IIa
383694	BD Nexiva™ Diffusics™ Closed IV Catheter System 20 GA 1.25 IN	Class IIa
383695	BD Nexiva™ Diffusics™ Closed IV Catheter System 18 GA 1.25 IN	Class IIa

Authorised Signatory:	
Name & Title:	Christopher Rogers, VP Regulatory Affairs
On behalf of:	Becton Dickinson Infusion Therapy Systems Inc.
Place of Issue:	9450 South State Street, Sandy, Utah 84070, USA
Date of Issue:	2026-04-14
Signature:	Signed by:   Signer Name: Christopher Rogers Signing Reason: I approve this document Signing Time: 15-Apr-2026 5:01:51 PM PDT 36DFBDC7D93A4EDD8A95BFA0996E41F6

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DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:																											
A	Original Release																											
B	Updated to Revision 06 of DoC template (CBI-058 FRM20)																											
C	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																											
D	STED Periodic Review (2025): Updated to new STED Template GFM-10128EE. No changes to the content of DoC.																											
E	CC-2025-272/ CC-2023-584: - Updated intended purpose clarity - Remove and Provide Last Lot Information for: <table><tr><th>SKU #</th><th>Product Name</th><th>Last Lot #</th><th>Last Lot Expiry Date</th></tr><tr><td>383590</td><td>BD Nexiva™ Diffusics™ Closed IV Catheter System 24 GA 0.75 IN</td><td>5335117</td><td>30-Nov-2028</td></tr><tr><td>383591</td><td>BD Nexiva™ Diffusics™ Closed IV Catheter System 22 GA 1.00 IN</td><td>5352361</td><td>31-Dec-2028</td></tr><tr><td>383592</td><td>BD Nexiva™ Diffusics™ Closed IV Catheter System 20 GA 1.00 IN</td><td>5338617</td><td>30-Nov-2028</td></tr><tr><td>383593</td><td>BD Nexiva™ Diffusics™ Closed IV Catheter System 20 GA 1.25 IN</td><td>5338618</td><td>30-Nov-2028</td></tr><tr><td>383594</td><td>BD Nexiva™ Diffusics™ Closed IV Catheter System 18 GA 1.25 IN</td><td>5338619</td><td>31-Dec-2028</td></tr></table>				SKU #	Product Name	Last Lot #	Last Lot Expiry Date	383590	BD Nexiva™ Diffusics™ Closed IV Catheter System 24 GA 0.75 IN	5335117	30-Nov-2028	383591	BD Nexiva™ Diffusics™ Closed IV Catheter System 22 GA 1.00 IN	5352361	31-Dec-2028	383592	BD Nexiva™ Diffusics™ Closed IV Catheter System 20 GA 1.00 IN	5338617	30-Nov-2028	383593	BD Nexiva™ Diffusics™ Closed IV Catheter System 20 GA 1.25 IN	5338618	30-Nov-2028	383594	BD Nexiva™ Diffusics™ Closed IV Catheter System 18 GA 1.25 IN	5338619	31-Dec-2028
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