



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 systems are intended to be inserted into a vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These devices 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.
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):	
<ul style="list-style-type: none">Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices	

Conformity Assessment Route:

<input checked="" type="checkbox"/> ANNEX IX Chapter I and III – Quality management System	EC CERTIFICATE No.: MDR 731353
<input type="checkbox"/> ANNEX IX Chapter II - Technical Documentation	EC CERTIFICATE No.:
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.:
<input type="checkbox"/> ANNEX XI Part A Production Quality Assurance	EC CERTIFICATE No.:
<input type="checkbox"/> ANNEX XI Part B Product Verification	EC CERTIFICATE No.:

☐ ANNEX II & III Technical Documentation

N/A

Common Specifications (CS):

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

Devices Covered by this DoC: *<only complete if more than one device is covered by this DoC>*

SKU#	Device Name	Device Class
383590	BD Nexiva™ Diffusics™ Closed IV Catheter System 24 GA 0.75 IN	Class IIa
383591	BD Nexiva™ Diffusics™ Closed IV Catheter System 22 GA 1.00 IN	Class IIa
383592	BD Nexiva™ Diffusics™ Closed IV Catheter System 20 GA 1.00 IN	Class IIa
383593	BD Nexiva™ Diffusics™ Closed IV Catheter System 20 GA 1.25 IN	Class IIa
383594	BD Nexiva™ Diffusics™ Closed IV Catheter System 18 GA 1.25 IN	Class IIa
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:	07-Mar-2024
Signature:	<div><div>DocuSigned by: Christopher Rogers</div><div><div></div><div>Signer Name: Christopher Rogers Signing Reason: I approve this document Signing Time: 07-Mar-2024 2:36:39 PM PST 36DFBDC7D93A4EDD8A95BFA0996E41F6</div></div></div>

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).



Version:	Detailed Change Description:
	Remove references to Regulation (EU) 207/2012 on electronic instructions for use of medical devices

**TEMPLATE Revision History:**

Rev	Revision Description	ECO Number	Requested By
06	Removed Certificate Expiration Date from Conformity Assessment Route section of the DoC. This is not required by 2017/745 and does not impact conformity assessment requirements. Modified European Authorized Representative Example in instructions from BD Switzerland to BD Ireland Limited.	500000325481	David Pieratos
05	Updated Authorized Signatory section to include a box with the statement "On behalf of" as well as provide guidance/instructions. This requirement MDR requirement for the DoC was missed in the Revision 4 update.	500000285045	Terri Krutz
04	Updated to include Chapter III in conformity assessment route option "ANNEX IX Chapter I – Quality management System" for all languages. Modified header to include Version Number as some businesses use SAP and others may use other approval and storage systems	500000283041	C. Pell
03	Updated to include Intended Purpose and guidance. Updated Revision History in Footer.	500000230219	David Pieratos
02	Based on recommendations from the BDX European Regulatory Affairs team, the DoC was reformatted to simplify the content to be in line with 2017/745 and MedTech Europe Guidance.	500000213116	Denise Oliveira
01	Original release.	500000190393	Jennifer Jaye