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 Venflon™ IV Cannula BD Venflon™ I IV Cannula
Basic UDI-DI:	038290FUCLEXAWAG
Risk Class and Rule:	Class IIa, Annex VIII, Rule 7
Intended Purpose	BD Venflon™ / Venflon™ I IV Cannula is designed to access the peripheral vasculature of the patient's blood system for rehydration, parenteral nutrition, medication delivery, blood transfusion, and monitoring purposes. The 22-18 GA (0.8-1.2 mm) devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa)
Notified Body:	BSI Group The Netherlands B.V. 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

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
391451	BD Venflon™ IV Cannula 22G 0.8 x 25mm	IIa
391452	BD Venflon™ IV Cannula 20G 1.0 x 32mm	IIa
391453	BD Venflon™ IV Cannula 18G 1.2 x 45mm	IIa
391454	BD Venflon™ IV Cannula 17G 1.4 x 45mm	IIa
391455	BD Venflon™ IV Cannula 16G 1.7 x 45mm	IIa
391456	BD Venflon™ IV Cannula 14G 2.0 x 45mm	IIa
391457	BD Venflon™ IV Cannula 18G 1.2 x 32mm	IIa
391491	BD Venflon™ IV Cannula 22G 0.8 x 25mm (India)	IIa
391492	BD Venflon™ IV Cannula 20G 1.0 x 32mm (India)	IIa
391493	BD Venflon™ IV Cannula 18G 1.2 x 45mm (India)	IIa
391495	BD Venflon™ IV Cannula 17G 1.4 x 45mm (India)	IIa
391496	BD Venflon™ IV Cannula 16G 1.7 x 45mm (India)	IIa
391891	BD Venflon™ I IV Cannula 22G 0.8 x 25mm	IIa
391892	BD Venflon™ I IV Cannula 20G 1.0 x 32mm	IIa
391893	BD Venflon™ I IV Cannula 18G 1.2 x 45mm	IIa
391895	BD Venflon™ I IV Cannula 16G 1.7 x 45mm	IIa
391896	BD Venflon™ I IV Cannula 14G 2.0 x 45mm	IIa
391591	BD Venflon™ I IV Cannula 22G 0.8 x 25mm (India)	IIa
391592	BD Venflon™ I IV Cannula 20G 1.0 x 32mm (India)	IIa
391593	BD Venflon™ I IV Cannula 18G 1.2 x 45mm (India)	IIa
391595	BD Venflon™ I IV Cannula 16G 1.7 x 45mm (India)	IIa
391596	BD Venflon™ I IV Cannula 14G 2.0 x 45mm (India)	IIa

Authorised Signatory:	
Name & Title:	Christopher Rogers, VP Regulatory Affairs
On behalf of:	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah 84070 USA
Place of Issue:	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah 84070 USA
Date of Issue:	2025-03-12
Signature:	Signed by: Christopher Rogers Signer Name: Christopher Rogers Signing Reason: I approve this document Signing Time: 13-Mar-2025 | 7:07:40 AM PDT 36DFBDC7D93A4EDD8A95BFA0996E41F6

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	New document, to align with EU MDR.
B	Remove Reference to Reg. (EU) 207/2012 per BD template requirements. 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 per the latest template revision. Update to new template form revision.

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