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™ Pro Safety Needle Protected IV Cannula BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology
Basic UDI-DI:	038290TBSJGPELDD (BD Venflon™ Pro Safety Needle Protected IV Cannula) 038290EJACFUASXJ (BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology)
Risk Class and Rule:	Class IIa, Annex VIII, Rule 7
Intended Purpose	BD Venflon™ Pro Safety Needle Protected IV Cannula and BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology are designed to access the peripheral vasculature of the patient's blood system for rehydration, parenteral nutrition, medication delivery, blood transfusion, and monitoring purposes. The 22-18G (0.9-1.3 mm) devices are suitable for use with power injectors set to 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
393222	BD Venflon™ Pro Safety Needle Protected IV Cannula 22G 0.9 x 25mm	IIa
393224	BD Venflon™ Pro Safety Needle Protected IV Cannula 20G 1.1 x 32mm	IIa
393226	BD Venflon™ Pro Safety Needle Protected IV Cannula 18G 1.3 x 32mm	IIa
393227	BD Venflon™ Pro Safety Needle Protected IV Cannula 18G 1.3 x 45mm	IIa
393228	BD Venflon™ Pro Safety Needle Protected IV Cannula 17G 1.5 x 45mm	IIa
393229	BD Venflon™ Pro Safety Needle Protected IV Cannula 16G 1.8 x 45mm	IIa
393230	BD Venflon™ Pro Safety Needle Protected IV Cannula 14G 2.0 x 45mm	IIa
393242	BD Venflon™ Pro Safety Needle Protected IV Cannula 22G 0.9 x 25mm (India)	IIa
393244	BD Venflon™ Pro Safety Needle Protected IV Cannula 20G 1.1 x 32mm (India)	IIa
393246	BD Venflon™ Pro Safety Needle Protected IV Cannula 18G 1.3 x 32mm (India)	IIa
393247	BD Venflon™ Pro Safety Needle Protected IV Cannula 18G 1.3 x 45mm (India)	IIa
393248	BD Venflon™ Pro Safety Needle Protected IV Cannula 17G 1.5 x 45mm (India)	IIa
393249	BD Venflon™ Pro Safety Needle Protected IV Cannula 16G 1.8 x 45mm (India)	IIa
393250	BD Venflon™ Pro Safety Needle Protected IV Cannula 14G 2.0 x 45mm (India)	IIa
393280	BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology 22G 0.9 x 25mm	IIa
393281	BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology 20G 1.1 x 25mm	IIa
393282	BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology 18G 1.3 x 32mm	IIa
393283	BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology 18G 1.3 x 45mm	IIa
393284	BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology 22G 0.9 x 25mm (India)	IIa
393285	BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology 20G 1.1 x 32mm (India)	IIa

393286	BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology 18G 1.3 x 32mm (India)	IIa
393287	BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology 18G 1.3 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 | 7:07:45 AM PDT 36DFBDC7D93A4EDD8A95BFA0996E41F6

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	New document, to align with EU MDR.
B	Added “BD” in front of “Instaflash™ Needle Technology”. Added “Needle Protected” after “Venflon Pro Safety”. Included BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology in Intended Purpose.
C	Remove Reference to Reg. (EU) 207/2012 per BD template requirements. Update to new template form revision.
D	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 current template revision CBI-058 FRM 20 Revision 6).

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