

**EU DECLARATION OF CONFORMITY (DoC)**

<b>Manufacturer:</b>	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah 84070 USA
<b>Manufacturer SRN:</b>	US-MF-000017719
<b>Authorised Representative:</b>	Becton Dickinson Ireland Ltd. Donore Road, Drogheda, Co. Louth A92 YW26, Ireland
<b>Authorised Representative SRN:</b>	IE-AR-000007610
<b>Product:</b>	BD Neoflon™ Pro IV Cannula
<b>Basic UDI-DI:</b>	038290ZCNOSRXLMV
<b>Risk Class and Rule:</b>	Class IIa, Annex VIII, Rule 7
<b>Intended Purpose:</b>	The BD Neoflon™ Pro IV Cannula is intended for infusions / injections and is designed to gain access to the peripheral vessels of the vascular system for IV therapy, blood transfusion and pressure monitoring.
<b>Notified Body:</b>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797
<p>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):</p> <ul style="list-style-type: none"><li>Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices</li><li>Regulation (EU) 207/2012 on electronic instructions for use of medical devices</li></ul>	

**Conformity Assessment Route:**



<input checked="" type="checkbox"/> ANNEX IX Chapter I and III – Quality management System	EC CERTIFICATE No.: MDR 731353 Certificate Expiration Date: 2027-03-23
<input type="checkbox"/> ANNEX IX Chapter II - Technical Documentation	EC CERTIFICATE No.: Certificate Expiration Date:
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: Certificate Expiration Date:
<input type="checkbox"/> ANNEX XI Part A Production Quality Assurance	EC CERTIFICATE No.: Certificate Expiration Date: pending
<input type="checkbox"/> ANNEX XI Part B Product Verification	EC CERTIFICATE No.: Certificate Expiration Date:
<input type="checkbox"/> ANNEX II & III Technical Documentation	N/A

**Common Specifications (CS):**

Number:	Title:	Full or Partial Application:
N/A	N/A	N/A

**Devices Covered by this DoC:**

SKU#	Device Name	Device Class
391379	BD Neoflon™ Pro IV Cannula 26G 0.6 x 19mm	Ila
391380	BD Neoflon™ Pro IV Cannula 24G 0.7 x 19mm	Ila
391389	BD Neoflon™ Pro IV Cannula 26G 0.6 x 19mm (India)	Ila
391390	BD Neoflon™ Pro IV Cannula 24G 0.7 x 19mm (India)	Ila

Authorised Signatory:	
Name & Title:	Kimberly Geisler, Associate Director 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:	2024-01-04
Signature:	<div>DocuSigned by:   Signer Name: Kimberly Geisler Signing Reason: I approve this document Signing Time: 04-Jan-2024   5:26:59 PM PST 10E7ED10D2904C68AEF18D5B195B796D</div>



BD   Becton Dickinson Infusion Therapy Systems Inc.	Document No. DC-070
Revision/Version: A	Page 3 of 4

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
A	New document, to align with EU MDR.

**TEMPLATE Revision History:**

Rev	Revision Description	ECO Number	Requested By
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