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 Insyte™ Autoguard™ Shielded IV Catheters BD Insyte™ Autoguard™ BC Pro Shielded IV Catheters
Basic UDI-DI:	038290KCPPHCMV8Y 038290TFYRGYXIPP 038290FYLKFOEMEG 038290HDSBCRGE3R 038290HDCOZIJX6T 038290OAODRZZNC9
Risk Class and Rule:	Class IIa, Annex VIII, Rule 7
Intended Purpose	BD Insyte™ Autoguard™ shielded IV catheters are intended to be inserted into a patient's peripheral 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. The 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa). BD Insyte™ Autoguard™ BC Pro shielded IV catheters are intended to be inserted into a patient's peripheral 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. The 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa).
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.:
☐ 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
381811	BD Insyte-N™ Autoguard™ Shielded IV Catheter	Class IIa
381812	BD Insyte™ Autoguard™ Shielded IV Catheter	Class IIa
381823	BD Insyte™ Autoguard™ Shielded IV Catheter	Class IIa
381833	BD Insyte™ Autoguard™ Shielded IV Catheter	Class IIa
381834	BD Insyte™ Autoguard™ Shielded IV Catheter	Class IIa
381837	BD Insyte™ Autoguard™ Shielded IV Catheter	Class IIa
381844	BD Insyte™ Autoguard™ Shielded IV Catheter	Class IIa
381847	BD Insyte™ Autoguard™ Shielded IV Catheter	Class IIa
381854	BD Insyte™ Autoguard™ Shielded IV Catheter	Class IIa
381857	BD Insyte™ Autoguard™ Shielded IV Catheter	Class IIa
381867	BD Insyte™ Autoguard™ Shielded IV Catheter	Class IIa
381911	BD Insyte-N™ Autoguard™ Winged Shielded IV Catheter	Class IIa
381912	BD Insyte™ Autoguard™ Winged Shielded IV Catheter	Class IIa

381923	BD Insyte™ Autoguard™ Winged Shielded IV Catheter	Class IIa
381933	BD Insyte™ Autoguard™ Winged Shielded IV Catheter	Class IIa
381934	BD Insyte™ Autoguard™ Winged Shielded IV Catheter	Class IIa
381937	BD Insyte™ Autoguard™ Winged Shielded IV Catheter	Class IIa
381944	BD Insyte™ Autoguard™ Winged Shielded IV Catheter	Class IIa
381947	BD Insyte™ Autoguard™ Winged Shielded IV Catheter	Class IIa
381954	BD Insyte™ Autoguard™ Winged Shielded IV Catheter	Class IIa
381957	BD Insyte™ Autoguard™ Winged Shielded IV Catheter	Class IIa
381012	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Class IIa
381023	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Class IIa
381024	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Class IIa
381033	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Class IIa
381034	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Class IIa
381037	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Class IIa
381044	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Class IIa
381047	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Class IIa
381054	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Class IIa
381057	BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Class IIa
382912	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	Class IIa
382923	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	Class IIa
382924	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	Class IIa
382933	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	Class IIa
382934	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	Class IIa
382937	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	Class IIa
382944	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	Class IIa
382947	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	Class IIa
382954	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	Class IIa
382957	BD Insyte™ Autoguard™ BC Pro Winged Shielded IV Catheter	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:	DocuSigned by: Christopher Rogers Signer Name: Christopher Rogers Signing Reason: I approve this document Signing Time: 07-Mar-2024 | 2:36:44 PM PST 36DFBDC7D93A4EDD8A95BFA0996E41F6

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Original Release
B	Updated to Revision 06 of DoC template (CBI-058 FRM20)
C	Corrected 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

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