EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, New Jersey 07417 USA
Manufacturer SRN:	US-MF-000019182
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road Co. Louth Drogheda, A92 YW26, Ireland
Authorised Representative SRN:	IE-AR-000007610
Product:	BD PosiFlush™ SP Syringes
Basic UDI-DI:	038290WKCQDZQWJK
Risk Class and Rule:	Class III, Annex VIII, Rule 14

Intended Purpose	BD PosiFlush™ SP Syringes are intended to be used FOR FLUSHING ONLY of in-situ peripheral intravenous catheters (PIVCs), peripherally inserted central catheters (PICCs), central venous catheters (CVCs), and implanted venous access ports. BD PosiFlush™ SP Syringe is not intended for dry product reconstitution, for medication dilution, or where intravenous therapy with sodium chloride is indicated. BD PosiFlush™ SP Syringe must not be used on a sterile field.
Notified Body:	National Standards Authority of Ireland (NSAI) 1, Swift square Northwood, Santry Dublin 9, Ireland Identification number : 0050
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.: 745.008 Certificate Expiration Date: 20 December 2027
☒ ANNEX IX Chapter II - Technical Documentation	EC CERTIFICATE No.: 745.008 Certificate Expiration Date: 20 December 2027
☐ ANNEX X Type Examination	EC CERTIFICATE No.: Certificate Expiration Date:
☐ ANNEX XI Part A Production QualityAssurance	EC CERTIFICATE No.: Certificate Expiration Date:
☐ ANNEX XI Part B Product Verification	EC CERTIFICATE No.: Certificate Expiration Date:
☐ ANNEX II & III Technical Documentation	N/A

Common Specifications (CS): Common Specifications have not been issued for this product.

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
306573	BD PosiFlush™ SP syringe CE 3mL	III
306574	BD PosiFlush™ SP syringe CE 5mL	III
306575	BD PosiFlush™ SP syringe CE 10mL	III
306583	BD PosiFlush™ SP syringe EMA 3mL	III
306584	BD PosiFlush™ SP syringe EMA 5mL	III
306585	BD PosiFlush™ SP syringe EMA 10mL	III
30657371	BD PosiFlush™ SP syringe India 3mL	III
30657471	BD PosiFlush™ SP syringe India 5mL	III
30657571	BD PosiFlush™ SP syringe India 10mL	III

Authorised Signatory:	
Name & Title:	John W. Roberts Regulatory Affairs Director Medication Delivery Solutions
On behalf of:	Becton, Dickinson and Company
Place of Issue:	BD Franklin Lakes, NJ, USA
Date of Issue:	22-Dec-2022
Signature:	DocuSigned by: John W Roberts 8B97BB78BFBD485... DS JWR

DECLARATION OF CONFORMITY Revision History:

Version:	Date:	Detailed Change Description:	Prepared by:
A	22 December 2022	New document created to meet MDR (EU) 2017/745 compliance.	Perrine Clert-Girard