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™ XS Syringes
Basic UDI-DI:	038290WKCQDZQWJK
Risk Class and Rule:	Class III, Annex VIII, Rule 14
Intended Purpose	BD PosiFlush™ XS 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™ XS Syringe is not intended for dry product reconstitution, for medication dilution, or where intravenous therapy with sodium chloride is indicated. Using aseptic technique, BD PosiFlush™ XS Syringe can 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
☒ ANNEX IX Chapter II - Technical Documentation	EC CERTIFICATE No.: 745.008D

Document: CCP-STED-002-DOC
Valid From: 05-Jun-2024 To: 31-Dec-9999
Print Date: 05-Jun-2024 13:35:10 GMT Daylight Time
Doc Type: ZRF
Doc Part: EN
Usage: Production Usage
Status: Released EFFECTIVE
Revision: N/A
Version: E
Change #: N/A
Classification: Confidential

☐ 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): 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
306570	BD PosiFlush™ XS Syringes 3ml	III
306571	BD PosiFlush™ XS Syringes 5ml	III
306572	BD PosiFlush™ XS Syringes 10ml	III
306580	BD PosiFlush™ XS Syringes 3ml EMA/CIS	III
306581	BD PosiFlush™ XS Syringes 5ml EMA/CIS	III
306582	BD PosiFlush™ XS Syringes 10ml EMA/CIS	III

Authorised Signatory:	
Name & Title:	John W Roberts Sr. Director Reg. Aff.
On behalf of:	Becton, Dickinson and Company
Place of Issue:	Franklin Lakes, NJ, USA
Date of Issue:	2024-06-05
Signature:	DocuSigned by: John W Roberts Signer Name: John W Roberts Signing Reason: I approve this document Signing Time: 05-Jun-2024 | 5:01:48 AM PDT 8B97BB78BFBD4856ABBFB5B27C5A103E

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
E	Annual review as per MS-QS-123 and update as per latest DoC template (rev.06).
D	Aligned products descriptions with 745.008D EU Technical Documentation Assessment Certificate.
C	Updated Technical Documentation certificate number.
B	Corrected page numbering.
A	New document created to meet MDR (EU) 2017/745 compliance.