EU Technical Documentation Assessment Certificate

Medical Device Regulation 2017/745

The National Standards Authority of Ireland (NSAI) as a duly designated Notified Body, (identification number 0050) for the purposes of the European Union under MDR 2017/745

HAS ASSESSED THE TECHNICAL DOCUMENTATION SUBMITTED BY

Becton, Dickinson and Company

1 Becton Drive
Franklin Lakes, NJ
07417, USA

Manufacturer SRN:	US-MF-000019182
Authorised Representative Name and Address:	Becton Dickinson Ireland Ltd. Donore Road County Louth Drogheda, A92 YW26, Ireland
Scope :	BD PosiFlush™ syringes
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. 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.

Conclusion: Technical documentation complies with the requirements of Annex IX, Chapter II *(where applicable with Section 5.1)* of MDR 2017/745.

Product Certificate Number:	745.008D	Re-Issued Date:	-
First Issue Date:	21 December 2022	Expiry Date:	20 December 2027
Site Certificate Number:	MD19.2305		

Signed:

Approved by:
Lisa Donlon
European Medical Device Operations Manager

Approved by:
Dr Majella Geraghty
European Medical Device Operations Manager

CONDITIONS AND LIMITATIONS: This certificate remains valid on condition that the Approved Quality Management System is maintained in an adequate and efficacious manner in line with the requirements of the Regulation and shall be subject to surveillance audits carried out by the Notified Body. This certificate is based on examination of identified relevant CS, harmonised standards, test reports and audit reports maintained on file with NSAI. Information on examination and tests as per Annex XII, section 10, is available on request. Changes which could affect conformity with the General Safety and Performance Requirements of MDR 2017/745 or with the conditions prescribed for use of the product must receive further approval from NSAI.

The validity of this certificate depends on conditions and/or is limited to the following:

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Appendix I			
Devices Covered by Certificate			
Model Number	Basic UDI-DI	Description	Risk Class
306573	038290WKCQDZQWJK	BD PosiFlush™ SP Syringes 3ml	III
306583	038290WKCQDZQWJK	BD PosiFlush™ SP Syringes 3ml EMA/CIS	III
30657371	038290WKCQDZQWJK	BD PosiFlush™ SP Syringes 3ml India	III
306574	038290WKCQDZQWJK	BD PosiFlush™ SP Syringes 5ml	III
306584	038290WKCQDZQWJK	BD PosiFlush™ SP Syringes 5ml EMA/CIS	III
30657471	038290WKCQDZQWJK	BD PosiFlush™ SP Syringes 5ml India	III
306575	038290WKCQDZQWJK	BD PosiFlush™ SP Syringes 10ml	III
306585	038290WKCQDZQWJK	BD PosiFlush™ SP Syringes 10ml EMA/CIS	III
30657571	038290WKCQDZQWJK	BD PosiFlush™ SP Syringes 10ml India	III
306570	038290WKCQDZQWJK	BD PosiFlush™ XS Syringes 3ml	III
306580	038290WKCQDZQWJK	BD PosiFlush™ XS Syringes 3ml EMA/CIS	III
306571	038290WKCQDZQWJK	BD PosiFlush™ XS Syringes 5ml	III
306581	038290WKCQDZQWJK	BD PosiFlush™ XS Syringes 5ml EMA/CIS	III
306572	038290WKCQDZQWJK	BD PosiFlush™ XS Syringes 10ml	III
306582	038290WKCQDZQWJK	BD PosiFlush™ XS Syringes 10ml EMA/CIS	III

Appendix II			
Certificate History			
Product Certificate Number	Date of Issue	Type of Change *[supplemented, modified or re-issued]*	Details of Change
n/a	n/a	n/a	n/a

EU Quality Management System Certificate

Medical Device Regulation 2017/745

The National Standards Authority of Ireland as a duly designated Notified Body, (0050) for the purposes of the European Union under MDR 2017/745

APPROVES THE QUALITY MANAGEMENT SYSTEM APPLIED BY

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ
07417, USA

Manufacturer SRN:	US-MF-000019182
Authorised Representative Name and Address:	Becton Dickinson Ireland Ltd. Donore Road County Louth Drogheda, A92 YW26, Ireland
Device Group:	BD PosiFlush™ syringes
Risk Class:	III

Intended Purpose

The 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.

The 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.

Conclusion: Quality Management System complies with the requirements of Annex IX, Chapter I & III of MDR 2017/745. The use of the NSAI Notified Body Identification Number 0050 in conjunction with CE Marking of Conformance for this product is hereby authorised.

Product Certificate Number:	745.008	Re-Issued Date:	-
First Issue Date:	21 December 2022	Expiry Date:	20 December 2027
Site Certificate Number:	MD19.2305		

Signed:

Approved by:
Lisa Donlon
European Medical Device Operations Manager

Approved by:
Dr Majella Geraghty
European Medical Device Operations Manager

CONDITIONS AND LIMITATIONS: this certificate remains valid on condition that the Approved Quality Management System is maintained in an adequate and efficacious manner in line with the requirements of the Regulation. This certificate is based on examination of identified relevant CS, harmonised standards, test reports and audit reports maintained on file with NSAI. Information on examination and tests as per Annex XII, section 10, is available on request. Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI. Substantial Changes to the QMS or the product range covered must receive further approval from NSAI.

The validity of this certificate depends on conditions and/or is limited to the following:

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Appendix I			
Certificate History			
Product Certificate Number	Date of Issue	Type of Change *[supplemented, modified or re-issued]*	Details of Change
n/a	n/a	n/a	n/a