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EC DECLARATION OF CONFORMITY

Manufacturer:	Becton Dickinson and Company 1 Becton Drive Franklin Lakes, New Jersey 07417 USA
Authorised Representative:	Becton Dickinson and Company Limited Donore Road Drogheda, Co Louth Ireland
Manufacturing Site(s):	**BD PosiFlush™ XS:** **3mL (306570, 306580), 5mL (306571, 306581), 10mL (306572, 306582):** Becton Dickinson and Company Donore Road Drogheda, Co Louth Ireland **BD PosiFlush™ SP** **10mL (306575, 306585):** • Becton Dickinson Medical Surgical 2153 12th Avenue Columbus, Nebraska 68601 USA • Becton Dickinson SA. C/Mequinenza, s/n, 22520 Fraga (Huesca) España • Becton Dickinson and Company Limited Donore Road Drogheda, Co Louth Ireland **5mL (306574, 306584):** • Becton Dickinson Medical Surgical 2153 12th Avenue

	Columbus, Nebraska 68601 USA • Becton Dickinson SA. C/Mequinenza, s/n, 22520 Fraga (Huesca) España **3mL (306573, 306583):** • Becton Dickinson Medical Surgical 2153 12th Avenue Columbus, Nebraska 68601 USA • Becton Dickinson SA. C/Mequinenza, s/n, 22520 Fraga (Huesca) España **10mL (30657571), 5mL (30657471) and 3mL (30657371) variant codes for India market:** • Becton Dickinson SA. C/Mequinenza, s/n, 22520 Fraga (Huesca) España
Products:	Pre-filled syringes with Sodium Chloride 0.9% for intravascular medical devices rinsing BD PosiFlush™ SP: ▪ 3mL (306573, 306583, 30657371) ▪ 5mL (306574, 306584, 30657471) ▪ 10mL (306575, 306585, 30657571) ▪ BD PosiFlush™ XS: ▪ 3mL (306570, 306580) ▪ 5mL (306571, 306581) ▪ 10mL (306572, 306582)
Classification:	Class III Medical Devices, Rule 13.
Conformity Assessment Route:	Annex III coupled with Annex V Annex VII
GMDN:	GMDN Code: **64786** GMDN Term: Vascular Catheter/cannula flush solution, non-anticoagulant, non-antimicrobial Definition: A solution (e.g., saline, sterile water) intended to flush the lumen of an in situ intravenous access device (IVAD), typically a peripheral intravenous

	cannula or central venous catheter, to maintain patency; it does not include an anticoagulant or antimicrobial agent. Also known as lock solution, the device is available in a small container (e.g., bottle) or prefilled syringe. This is a single-use device.

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer.

Harmonised Standards:	EN 556-1:2001, EN 1041:2008, EN 62366:2008, EN ISO 15223-1:2016, EN ISO 10993-1:2009, EN ISO 10993-4:2009, EN ISO 10993-5:2009, EN ISO 10993-11:2009, EN ISO 10993-12:2012, EN ISO 10993-17:2009, EN ISO 10993-18:2009, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 17665-1:2006, EN 1707:1996, EN 20594-1:1993, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN 22442 :2007
Non-Harmonised Standards:	BS EN 540:1993, ICH Q1A guidance, ISO 14644:2000, USP <42>, ISO 10993-10:2010
Notified Body:	National Standards Authority of Ireland (NSAI) 1, Swift square Northwood, Santry Dublin 9, Ireland Identification number : 0050 Laboratoire National de Métrologie et d'Essai LNE-GMED 1 rue Gaston Boissier 75724 Paris Cedex 15 Identification number : 0459
EC Certificate Number	NSAI Annex V CE Certificate: 252.780 BD PosiFlush™ SP : LNE/GMED Annex III CE Certificate N°16730 BD PosiFlush™ XS : LNE/GMED Annex III CE Certificate N°14879
Date of issuance of the original CE certificate	Certificate: 252.780 original issuance: January 29th, 2009 Certificate N°16730 original issuance: August 4th, 2009 Certificate N°14879 original issuance: November 17th, 2008

Date: 2 Oct 2020

Signature .....

John W. Roberts
Regulatory Affairs Director
BD Medical – Medical & Procedural Solutions

Date: 10/6/2020

Signature DocuSigned by: 1EB97F1ADC4C471...

Diarmuid CALLAGHAN
Associate Director Quality
BD Medical – Medical & Procedural Solutions

REVISION HISTORY Current Revision Prepared By: Perrine CLERT-GIRARD		
REV.	**Revision Description**	**Releasing ECO/ECR**
01	Initial Release Formatting to new template: • Include GMDN code and initial issuance date of CE certificates • Update standards	
02	Update with Drogheda site for PosiFlush SP 10mL manufacturing (306575, 306585)	
03	Update of Fraga new manufacturing site for PosiFlush SP 10mL (306575, 306585) and PosiFlush 5mL (306574, 306584)	
04	EN 980 replaced by ISO 15223-1	
05	Addition of Fraga as manufacturing site for PosiFlush SP 3mL (306573, 306583)	
A	Initial release SAP, addition of list of non-harmonized standards, update of list of harmonized standard, addition of India Variant Catalog Number and addition of signature of EC Rep	
B	Replaced GMDN code with the new one (previous one has been made obsolete).	