BD Medical, Medical Surgical Systems
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Donore Road
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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 Donore Road Drogheda, Co Louth Ireland
Products:	Pre-filled syringes with Sodium Chloride 0.9% for intravascular medical devices rinsing BD PosiFlush™ SP: ▪ 3mL (306573, 306583) ▪ 5mL (306574, 306584) ▪ 10mL (306575, 306585) ▪ BD PosiFlush™ XS: ▪ 3mL (306570, 306580) ▪ 5mL (306571, 306581) ▪ 10mL (306572, 306582)
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

	3mL (306573, 306583), 5mL (306574, 306584): • Becton Dickinson Medical Surgical 2153 12th Avenue Columbus, Nebraska 68601 USA
Classification:	Class III Medical Devices
Conformity Assessment Route:	Annex III coupled with Annex V Annex VII
GMDN:	GMDN Code: **46309** GMDN Term: Vascular catheter flush syringe Definition: A device used to wash-out a vascular access catheter in situ with a rush of solution It is a piston-in-cylinder prefilled with a saline or low-dose heparin solution, and is typically used when a patient has an intravenous (IV) access device in place. It is not intended for dry product reconstitution, for medication dilution, or where IV therapy with sodium chloride (NaCl) or heparin is indicated. 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.

List of Harmonised Standards:	EN 556-1:2001, EN 1041:2008, EN 62366:2008, EN 22442:2007, EN 980:2008, EN ISO 10993 series, EN ISO 13485:2012, 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
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 PosiFlushTM SP : LNE/GMED Annex III CE Certificate N°16730 BD PosiFlushTM 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: Jan 20, 2017

Signature.....

John Blewitt
Regulatory Affairs Manager

BD Medical – Medical & Procedural Solutions

REVISION HISTORY		
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	