



## EU DECLARATION OF CONFORMITY (DoC)

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

<b>Intended Purpose</b>	<p>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.</p> <p>BD PosiFlush™ SP Syringe is not intended for dry product reconstitution, for medication dilution, or where intravenous therapy with sodium chloride is indicated.</p> <p>BD PosiFlush™ SP Syringe must not be used on a sterile field.</p>
<b>Notified Body:</b>	<p>National Standards Authority of Ireland (NSAI)</p> <p>1, Swift square</p> <p>Northwood, Santry</p> <p>Dublin 9, Ireland</p> <p>Identification number : 0050</p>
<p>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):</p> <ul style="list-style-type: none"> <li>Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices</li> </ul>	

### Conformity Assessment Route:

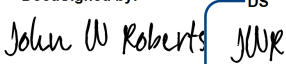
<input checked="" type="checkbox"/> ANNEX IX Chapter I and III – Quality Management System	<p>EC CERTIFICATE No.: 745.008</p> <p>Certificate Expiration Date: 20 December 2027</p>
<input checked="" type="checkbox"/> ANNEX IX Chapter II - Technical Documentation	<p>EC CERTIFICATE No.: 745.008</p> <p>Certificate Expiration Date: 20 December 2027</p>
<input type="checkbox"/> ANNEX X Type Examination	<p>EC CERTIFICATE No.:</p> <p>Certificate Expiration Date:</p>
<input type="checkbox"/> ANNEX XI Part A Production Quality Assurance	<p>EC CERTIFICATE No.:</p> <p>Certificate Expiration Date:</p>
<input type="checkbox"/> ANNEX XI Part B Product Verification	<p>EC CERTIFICATE No.:</p> <p>Certificate Expiration Date:</p>
<input type="checkbox"/> 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:	
<b>Name &amp; Title:</b>	John W. Roberts Regulatory Affairs Director Medication Delivery Solutions
<b>On behalf of:</b>	Becton, Dickinson and Company
<b>Place of Issue:</b>	
<b>Date of Issue:</b>	
<b>Signature:</b>	<div>DocuSigned by:  8B97BB78BFD485...</div>

**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