



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 Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland
Authorised Representative SRN:	IE-AR-000007610
Product:	BD PureHub™ Disinfecting Cap: <ul style="list-style-type: none">• Bulk Single Unit Disinfecting Cap (306598)• IV Pole Strip Unit Disinfecting Cap (306599)
Basic UDI-DI:	038290EHFSXNCJ8K
Risk Class and Rule:	Class IIa, Annex VIII, Rule 16

Intended Purpose	<p>BD PureHub™ Disinfecting Cap is intended to be used as a disinfecting device for swabbable needle-free luer connectors prior to I.V. access and to act as a physical barrier between line accesses.</p> <p>BD PureHub™ Disinfecting Cap will disinfect the needle-free luer connector one minute after application and act as a physical barrier for up to seven days, if not removed.</p>
Notified Body:	<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"> Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices 	

Conformity Assessment Route:

<input checked="" type="checkbox"/> ANNEX IX Chapter I and III – Quality management System	<p>EC CERTIFICATE No.: 745.117</p> <p>Certificate Expiration Date: 20 December 2027</p>
<input type="checkbox"/> ANNEX IX Chapter II - Technical Documentation	<p>EC CERTIFICATE No.:</p> <p>Certificate Expiration Date:</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
306598	BD PureHub™ Disinfecting Cap Single	IIa
306599	BD PureHub™ Disinfecting Cap IV Pole Strip	IIa

Authorised Signatory:

Name & Title:	John W. Roberts Regulatory Affairs Director Medication Delivery Solutions
On behalf of:	Becton Dickinson and Company
Place of Issue:	BD Franklin Lakes, NJ, USA
Date of Issue:	22-Dec-2022
Signature:	<div>DocuSigned by:  John Roberts</div>

Signer Name: John Roberts
Signing Reason: I approve this document
Signing Time: 22-Dec-2022 | 8:23:27 AM EST
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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.	Marine Martinez de Murguia