

**EU DECLARATION OF CONFORMITY (DoC)**

<b>Manufacturer:</b>	Becton Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 USA
<b>Manufacturer SRN:</b>	US-MF-000019182
<b>Authorised Representative:</b>	Becton Dickinson Ireland Ltd. Donore Road Drogheda Co. Louth A92 YW26 Ireland
<b>Authorised Representative SRN:</b>	IE-AR-000007610
<b>Product:</b>	BD AutoShield Duo™ and BD SafeAssist™
<b>Basic UDI-DI:</b>	<b>BD AutoShield Duo™: 038290DZHUGQWQJ4</b> <b>BD SafeAssist™: 038290BRBHZCTA6F</b>
<b>Risk Class and Rule:</b>	Class IIa, Annex VIII, Rule 6
<b>Intended Purpose</b>	<p>BD AutoShield Duo™ Safety Pen Needles are intended for use with pen injector devices for the injection of drugs by health care professionals or laypersons, in a hospital or home setting. The device is a single use sterile needle designed to reduce occurrence of accidental needle sticks from both ends of the needle by providing two safety shields, which lock in place after use (patient-end) and upon removal of the needle from the pen (pen connection-end).</p> <p>BD SafeAssist™ Safety Pen Needles are intended for use with pen injector devices for the injection of drugs by health care professionals or laypersons, in a hospital or home setting. The device is a single use sterile needle designed to reduce occurrence of accidental needle sticks from the patient end of the needle by providing a safety shield that locks over the needle after use.</p>
<b>Notified Body:</b>	NSAI (National Standards Authority of Ireland) 1 Swift Square, Northwood, Santry, Dublin 9, Ireland Notified Body Number: 0050
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):	
<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	EC CERTIFICATE No.: <b>745.021</b> Certificate Expiration Date: <b>12.22.2027</b>
<input type="checkbox"/> ANNEX IX Chapter II - Technical Documentation	EC CERTIFICATE No.:      Certificate Expiration Date:
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: Certificate Expiration Date:
<input type="checkbox"/> ANNEX XI Part A Production Quality Assurance	EC CERTIFICATE No.: Certificate Expiration Date:
<input type="checkbox"/> ANNEX XI Part B Product Verification	EC CERTIFICATE No.: Certificate Expiration Date:
<input type="checkbox"/> ANNEX II & III Technical Documentation	N/A

**Common Specifications (CS):**


Number: <Version/Year>	Title:	Full or Partial Application: <Justification>
N/A	N/A	N/A

This CS table is intentionally blank. No common specifications have been identified for BD AutoShield Duo™ and BD SafeAssist™.

**Devices Covered by this DoC:**

SKU#	Device Name	Device Class
329505	BD AutoShield Duo™	Ila
329535	BD AutoShield Duo™	Ila
329605	BD AutoShield Duo™	Ila
329608	BD AutoShield Duo™	Ila
329916	BD SafeAssist™	Ila
329917	BD SafeAssist™	Ila

**Authorised Signatory:**

<b>Name &amp; Title:</b>	Heather Reed VP Global Regulatory Affairs
<b>On behalf of:</b>	Becton Dickinson and Company
<b>Place of Issue</b>	1 Becton Drive, Franklin Lakes, NJ 07417, USA
<b>Date of Issue:</b>	26 July 2023
<b>Signature:</b>	

**DECLARATION OF CONFORMITY Revision History:**

<b>Version:</b>	<b>Detailed Change Description:</b>
1	New document created to meet MDR (EU) 2017/745 compliance
2	Update according to the latest template version and removal of discontinued reference 329705