

**EU DECLARATION OF CONFORMITY (DoC)**

Manufacturer:	Becton Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 USA
Manufacturer SRN:	US-MF-000019182
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road Drogheda Co. Louth A92 YW26 Ireland
Authorised Representative SRN:	IE-AR-000007610
Product:	BD AutoShield Duo™ and BD SafeAssist™
Basic UDI-DI:	BD AutoShield Duo™: 038290DZHUGQWQJ4 BD SafeAssist™: 038290BRBHZCTA6F
Risk Class and Rule:	Class IIa, Annex VIII, Rule 6
Intended Purpose	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). 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.
Notified Body:	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): Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices	

**Conformity Assessment Route:**

☒ ANNEX IX Chapter I and III – Quality management System	EC CERTIFICATE No.: 745.021 Certificate Expiration Date: 12.22.2027
☐ ANNEX IX Chapter II - Technical Documentation	EC CERTIFICATE No.: Certificate Expiration Date:
☐ ANNEX X Type Examination	EC CERTIFICATE No.: Certificate Expiration Date:
☐ ANNEX XI Part A Production Quality Assurance	EC CERTIFICATE No.: Certificate Expiration Date:
☐ ANNEX XI Part B Product Verification	EC CERTIFICATE No.: Certificate Expiration Date:
☐ 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:**

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

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
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