



EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152, USA		
Manufacturer SRN:	US-MF-000018910		
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26, Ireland		
Authorised Representative SRN:	IE-AR-000007610		
Product:	Catalog Number	Product Trade Name	
	221606	BD BBL™ Port-A-Cul™ Tube	
	221608	BD BBL™ Port-A-Cul™ Vial	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	221606	BD BBL™ Port-A-Cul™ Tube	038290BIMUXPFIBD
	221608	BD BBL™ Port-A-Cul™ Vial	038290KXVIOYIBPH
Risk Class and Rule :	Class A, Rule 5(c)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	221606	BD BBL™ Port-A-Cul™ Tube	BD BBL Port-a-Cul Tubes contain a reduced transport medium and are intended to maintain the viability of anaerobic, facultative and aerobic microorganisms, present in swab specimens, during transport from the patient to the laboratory.
	221608	BD BBL™ Port-A-Cul™ Vial	BD BBL Port-A-Cul Vials contain a reduced transport medium and are intended to maintain the viability of anaerobic, facultative and aerobic microorganisms, present in fluid specimens, during transport from the patient to the laboratory.

**Notified Body:**

Not applicable, devices self-certified.

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) 2017/746 on *In Vitro* Diagnostic Medical Devices.

Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input checked="" type="checkbox"/> ANNEX I & II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common Specifications have not been issued for this products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
221606	BD BBL™ Port-A-Cul™ Tube	Class A
221608	BD BBL™ Port-A-Cul™ Vial	Class A

Authorised Signatory:

Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	Becton, Dickinson and Company
Place of Issue:	Sparks, MD, USA

**Date of Issue:**

10-Nov-2022

Signature:

DocuSigned by:

Anne Zavertnik

Signer Name: Anne Zavertnik

Signing Reason: I approve this document

Signing Time: 10-Nov-2022 | 11:34:09 PM GMT

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DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Minor formatting changes.
03	Revision 04 Template Change, updated details in Product, Basic UDI-DI and Intended Purpose to tabular format, removed not available from common specifications table and Formatting changes were made.