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
221607	BD BBL™ Port-A-Cul™ Tube and Swabs Sterile Pack
221609	BD BBL™ Port-A-Cul™ Vial Sterile Pack
221602	BD BBL™ Port-A-Cul™ Transport Jar Sterile Pack

Basic UDI-DI:

Catalog Number	Product Trade Name	Basic UDI-DI
221607	BD BBL™ Port-A-Cul™ Tube and Swabs Sterile Pack	038290OLERBANTAP
221609	BD BBL™ Port-A-Cul™ Vial Sterile Pack	038290FGROSVKVDS
221602	BD BBL™ Port-A-Cul™ Transport Jar Sterile Pack	038290OLERBANTAP

Risk Class and Rule : Class A-Sterile, Rule 5(c)

Intended Purpose:

Catalog Number	Product Trade Name	Intended Purpose
221607	BD BBL™ Port-A-Cul™ Tube and Swabs Sterile Pack	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 manually collected swab specimens, during transport from the patient to the laboratory. Sterile packages are for collection of specimens in clean areas; e.g., surgical suites.
221609	BD BBL™ Port-A-Cul™ Vial Sterile Pack	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 manually collected fluid specimens, during transport from the patient to the laboratory. Sterile packages are for collection of specimens in clean areas; e.g., surgical suites.
	221602	BD BBL™ Port-A-Cul™ Transport Jar Sterile Pack	BD BBL Port-A-Cul Transport Jars contain a reduced transport medium and are intended to maintain the viability of anaerobic, facultative and aerobic microorganisms, present in manually collected tissue and biopsy specimens, during transport from the patient to the laboratory. Sterile packages are for collection of specimens in clean areas; e.g., surgical suites.
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797		
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:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☒ ANNEX IX Full Quality System	EC CERTIFICATE No.: IVDR 750848 EC Certificate Expiration Date: 2027-05-22
☐ ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☒ ANNEX XI Production Quality System	EC CERTIFICATE No.: IVDR 750848 EC Certificate Expiration Date: 2027-05-22
☐ ANNEX I & II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common specifications have not been issued for these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
221607	BD BBL™ Port-A-Cul™ Tube and Swabs Sterile Pack	Class A (Sterile)
221609	BD BBL™ Port-A-Cul™ Vial Sterile Pack	Class A (Sterile)
221602	BD BBL™ Port-A-Cul™ Transport Jar Sterile Pack	Class A (Sterile)

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 | 11:34:17 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	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.