EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton Dickinson Inc. 7 Loveton Circle Sparks, MD 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:	**SKU**	**Description**	
	443924	BD Molecular Urine Transport Kit	
	443925	BD Molecular Swab Collection Kit	
	440296	BD Molecular Swab Sample Buffer Tubes	
	443923	BD Molecular LBC Sample Buffer Tubes	
	443977	BD CTGC LBC Diluent for BD COR™ System	
Basic UDI-DI:	**SKU**	**Description**	**UDI-DI**
	443924	BD Molecular Urine Transport Kit	038290PBLLRGFPA7
	443925	BD Molecular Swab Collection Kit	038290PDWYCWZOM8
	440296	BD Molecular Swab Sample Buffer Tubes	038290PDWYCWZOM8
	443923	BD Molecular LBC Sample Buffer Tubes	038290PEBGAXBO4H
	443977	BD CTGC LBC Diluent for BD COR™ System	038290PEBGAXBO4H
Risk Class and Rule:	Class A, Rule 5 (c)		
Intended Purpose:	**BD Molecular Urine Transport Kit (443924)** The BD Molecular Urine Transport Kit is intended to be used in clinical settings according to the instructions provided for collection, preservation, and transport of urine specimens. This transport system is for use for testing with the BD Molecular products.		
	BD Molecular Swab Collection Kit (443925) and **BD Molecular Swab Sample Buffer Tubes (440296)** The BD Molecular Swab Collection Kit is intended to be used in clinical settings according to the instructions provided for collection and transport of vaginal and endocervical swab specimens. This transport system is for use for testing with BD Molecular products.		

	BD Molecular LBC Sample Buffer Tubes (443923) The BD Molecular LBC Sample Buffer Tubes are intended to be used in clinical settings according to the instructions provided for the preservation and transport of Liquid-Based Cytology (LBC) specimens. This transport system is for use for testing with the BD Molecular products.
	BD CTGC LBC Diluent for BD COR™ System (443977) The BD CTGC LBC Diluent for BD COR™ System is for automated aliquoting of LBC specimens on the BD COR™ System.
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:

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

Common Specifications (CS):

Number:	Title:	Full or Partial Application:
Not Available	Not Available	Not Available

Common specifications have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
443924	BD Molecular Urine Transport Kit	Class A
443925	BD Molecular Swab Collection Kit	Class A
440296	BD Molecular Swab Sample Buffer Tubes	Class A
443923	BD Molecular LBC Sample Buffer Tubes	Class A
443977	BD CTGC LBC Diluent for BD COR™ System	Class A

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
Place of Issue:	Sparks, MD, USA
Date of Issue:	19-May-2022
Signature:	DocuSigned by: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 19-May-2022 | 1:34:09 PM BST DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial Release

TEMPLATE Revision History:

Rev	Revision Description	ECO Number	Requested By
03	Updated template to include Intended Purpose and instructions. Updated footer to Revision 3.	500000230219	David Pieratos
02	Based on recommendations from the BDX European Regulatory Affairs team, the DoC was reformatted to simplify the content to be in line with 2017/746 and MedTech Europe Guidance.	500000213116	Denise Oliveira
01	Original release.	500000190393	Jennifer Jaye