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**	
	443989	BD COR™ MX	
Basic UDI-DI:	**SKU**	**Description**	**UDI-DI**
	443989	BD COR™ MX	038290PAODHOBV77
Risk Class and Rule:	Class A, Rule 5 (b)		
Intended Purpose:	The BD COR™MX instrument will perform the assay processing steps of the available molecular tests, including extraction, amplification, and transfer of information to the BD COR™ System software for analysis and reporting.		
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.
- Directive 2014/30/EU of the European Parliament and of the Council on Medical Devices relating to electromagnetic compatibility

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
443989	BD COR™ MX	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 | 1:26:55 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