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**: 437519 — **Product Trade Name**: BD PCR Cartridge
Basic UDI-DI:	**Catalog Number**: 437519 — **Product Trade Name**: BD PCR Cartridge — **Basic UDI-DI**: 038290YMCUPXTNQ8
Risk Class and Rule:	Class A, Rule 5 (a)
Intended Purpose:	**Catalog Number**: 437519 — **Product Trade Name**: BD PCR Cartridge — **Intended Purpose**: The BD PCR Cartridge is an accessory intended to be used with the assays performed on the BD MAX System and the BD COR MX System. It contains microfluidic channels made of disposable plastic utilized by the Systems to perform automated nucleic acid amplification and detection of nucleic acid from multiple specimen types.
Notified Body:	Not applicable, device 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.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☒ ANNEX I & II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common Specifications have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
437519	BD PCR Cartridge	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 | 11:33:01 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial Release
02	Changed to CBI-058 FRM24 (IVDR DoC) Revision 4 template. Catalog No column included in intended purpose, product and Basic UDI-DI sections. Removed "Not available" from common specification table. Updated "On behalf of" with Legal Manufacturer's Name. Included Catalog, Device name and Class in Devices Covered by this DoC. Formatting changes.