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 No.	Product Trade Name
491103	BD PrepMate™ Automated Accessory

Basic UDI-DI:

Catalog No.	Product Trade Name	Basic UDI-DI
491103	BD PrepMate™ Automated Accessory	038290XFQQTAMRM4

Risk Class and Rule:	Class A, Rule 5 (b)
Intended Purpose:	

Catalog No.	Product Trade Name	Intended Purpose
491103	BD PrepMate™ Automated Accessory	The BD PrepMate ™ Automated Accessory is an accessory to the BD SurePath Liquid-based Pap Test, the BD PrepStain Slide Processor, and the BD Totalys SlidePrep. The BD PrepMate Automated Accessory automates the initial

			enrichment process of mixing and dispensing the specimen over BD Density Reagent. The BD PrepMate Automated Accessory mixes and removes the specimen from a BD SurePath Collection Vial or BD CytoRich Clear Vial. It then layers the specimen onto the density reagent in a centrifuge tube. The automated process handles from one to twelve specimens per cycle.
Notified Body:	Not applicable, device(s) 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 2011/65/EU as amended (EU) 2015/863 on Restriction of the use of certain hazardous substances in electrical and electronic equipment as amended by Commission Delegated Directive 2015/863 (RoHS)

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
491103	BD PrepMate™ Automated Accessory	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 | 11:30:15 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release.
02	Updated to remove WEEE Directive as it is not a CE-marking regulation. Minor formatting changes.
03	Revision 04 Template change, ‘Assigned BUDI’ changed to ‘Basic UDI-DI’, Intended Purpose updated in Table Format, Removed ‘Not Available’ in Common Specification table, Legal manufacturer name updated in Authorised signatory section