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
443327	BD Totalys™ MultiProcessor

Basic UDI-DI:

Catalog No.	Product Trade Name	Basic UDI-DI
443327	BD Totalys™ MultiProcessor	038290CEMRFSQF67

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

Catalog No.	Product Trade Name	Intended Purpose
443327	BD Totalys™ MultiProcessor	The BD Totalys™ MultiProcessor is used in conjunction with the BD Totalys™ SlidePrep to prepare the BD SurePath™ Liquid-based Pap Test, which is intended as a replacement for the conventional gynecologic Pap smear. The BD SurePath™ test is intended for use in the screening and

			detection of cervical cancer, pre-cancerous cervical lesions, atypical cells and all other cytological categories as defined by The Bethesda System for Reporting Cervical/Vaginal Cytological Diagnoses. The BD Totalys™ MultiProcessor automates the preparation of an enriched cell pellet from a cervical cytology specimen collected in a BD SurePath™ Collection Vial. The cell pellet produced by the BD Totalys™ MultiProcessor is transferred to the BD Totalys™ SlidePrep for further processing to prepare a BD SurePath™ slide. The BD Totalys™ MultiProcessor can be programmed to perform the optional withdrawal of a 0.5 mL aliquot from the BD SurePath™ Collection Vial, prior to the cell enrichment process, for ancillary testing indicated for use with the BD Totalys™ MultiProcessor. If a 0.5 mL aliquot is not withdrawn prior to cytology processing and slide preparation, the BD Totalys™ MultiProcessor can transfer a 0.25-1.5 mL aliquot of the residual material from the BD SurePath™ Collection Vial for ancillary testing indicated for use with the BD Totalys™ MultiProcessor. Additionally, the BD Totalys™ MultiProcessor may be used to re-process archived BD SurePath™ cytology specimens into cell pellets. The BD Totalys™

				MultiProcessor can provide chain of custody information, linking the output cell pellets and molecular tubes to the originating BD SurePath™ Collection Vial.
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
443327	BD Totalys™ MultiProcessor	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 | 11:30:00 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release.
02	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