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	Product Trade Name
212522	BD BBL™ TB Stain Kit K
212520	BD BBL™ TB Stain Kit ZN
212519	BD BBL™ TB Fluorescent Stain Kit M
212521	BD BBL™ TB Fluorescent Stain Kit T
212514	BD BBL™ TB Auramine M
212515	BD BBL™ TB Auramine-Rhodamine T
212523	BD BBL™ TB Brilliant Green K
212518	BD BBL™ TB Carbolfuchsin KF
212511	BD BBL™ TB Carbolfuchsin ZN
212517	BD BBL™ TB Decolorizer
212512	BD BBL™ TB Decolorizer TM
212516	BD BBL™ TB Methylene Blue
212513	BD BBL™ TB Potassium Permanganate
231391	BD BBL™ AFB Slide

Basic UDI-DI:

Catalog Number	Product Trade Name	Basic UDI-DI
212522	BD BBL™ TB Stain Kit K	038290DNIVLTFBBH
212520	BD BBL™ TB Stain Kit ZN	

212519	BD BBL™ TB Fluorescent Stain Kit M	
212521	BD BBL™ TB Fluorescent Stain Kit T	
212514	BD BBL™ TB Auramine M	
212515	BD BBL™ TB Auramine-Rhodamine T	
212523	BD BBL™ TB Brilliant Green K	
212518	BD BBL™ TB Carbolfuchsin KF	
212511	BD BBL™ TB Carbolfuchsin ZN	
212517	BD BBL™ TB Decolorizer	
212512	BD BBL™ TB Decolorizer TM	
212516	BD BBL™ TB Methylene Blue	
212513	BD BBL™ TB Potassium Permanganate	038290IBRDUENQ6V
231391	BD BBL™ AFB Slide	038290IBBABEPZTU

Risk Class and Rule : Class A, Rule 5 (a)

Intended Purpose:

Catalog Number	Product Trade Name	Intended Purpose
212522	BD BBL™ TB Stain Kit K	BD BBL™ TB Stain Kits are used to manually stain smears prepared from specimens and cultures suspected of containing mycobacteria for qualitative early presumptive diagnosis of mycobacterial infection and characterization of bacterial isolates.
212520	BD BBL™ TB Stain Kit ZN	
212519	BD BBL™ TB Fluorescent Stain Kit M	

212521	BD BBL™ TB Fluorescent Stain Kit T		
212514	BD BBL™ TB Auramine M		
212515	BD BBL™ TB Auramine-Rhodamine T		
212523	BD BBL™ TB Brilliant Green K		
212518	BD BBL™ TB Carbolfuchsin KF		
212511	BD BBL™ TB Carbolfuchsin ZN		
212517	BD BBL™ TB Decolorizer		
212512	BD BBL™ TB Decolorizer TM		
212516	BD BBL™ TB Methylene Blue		
212513	BD BBL™ TB Potassium Permanganate		
231391	BD BBL™ AFB Slide	The BD BBL™ AFB Slide is used for evaluating and controlling the quality of acid-fast and fluorescent stain reagents and staining techniques for the detection of acid-fast bacilli (AFB).	

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.: 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 these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
212522	BD BBL™ TB Stain Kit K	Class A
212520	BD BBL™ TB Stain Kit ZN	Class A
212519	BD BBL™ TB Fluorescent Stain Kit M	Class A
212521	BD BBL™ TB Fluorescent Stain Kit T	Class A
212514	BD BBL™ TB Auramine M	Class A
212515	BD BBL™ TB Auramine-Rhodamine T	Class A
212523	BD BBL™ TB Brilliant Green K	Class A
212518	BD BBL™ TB Carbolfuchsin KF	Class A
212511	BD BBL™ TB Carbolfuchsin ZN	Class A
212517	BD BBL™ TB Decolorizer	Class A
212512	BD BBL™ TB Decolorizer TM	Class A
212516	BD BBL™ TB Methylene Blue	Class A
212513	BD BBL™ TB Potassium Permanganate	Class A
231391	BD BBL™ AFB Slide	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 | 11:35:30 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template change, Catalog number and product trade name included in the Intended Purpose Section, removed rule from Devices covered by this DoC table, removed the word not available from common specifications table and formatting changes.