

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	
	240862	BD BBL™ MycoPrep™ Kit	
	240863	BD BBL™ MycoPrep™ Kit	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	240862	BD BBL™ MycoPrep™ Kit	038290JICVJPSKAP
	240863	BD BBL™ MycoPrep™ Kit	038290JICVJPSKAP
Risk Class and Rule :	Class A, Rule 5(a)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	240862	BD BBL™ MycoPrep™ Kit	The BD BBL MycoPrep Kits are used for the digestion and decontamination of clinical specimens suspected to contain mycobacteria, especially <i>Mycobacterium tuberculosis</i> .
	240863	BD BBL™ MycoPrep™ Kit	
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): <ul style="list-style-type: none"> Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices. 			

Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.:N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.:N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.:N/A EC Certificate Expiration Date: N/A
<input checked="" type="checkbox"/> 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
240862	BD BBL™ MycoPrep™ Kit	Class A
240863	BD BBL™ MycoPrep™ Kit	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:	<div><div>DocuSigned by:</div><div>Anne Zavertnik</div><div><div></div><div>Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:32:47 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div></div></div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template Change, updated details in Product, Basic UDI-DI and Intended Purpose to tabular format, removed not available from common specifications table and Formatting changes were made.