

EU DECLARATION OF CONFORMITY (DoC)

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|---|---|---------------------------|---------------------|
| 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: | BD BBL™ MycoPrep™ Kit (Catalog: 240862, 240863) | | |
| 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: | The BD BBL MycoPrep Kits are used for the digestion and decontamination of clinical specimens suspected to contain mycobacteria, especially <i>Mycobacterium tuberculosis</i> . | | |
| 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:

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| <input type="checkbox"/> ANNEX IX Technical File Examination | EC CERTIFICATE No.: EC Certificate Expiration Date: |
| <input type="checkbox"/> ANNEX IX Full Quality System | EC CERTIFICATE No.: EC Certificate Expiration Date: |
| <input type="checkbox"/> ANNEX X Type Examination | EC CERTIFICATE No.: EC Certificate Expiration Date: |
| <input type="checkbox"/> ANNEX XI Production Quality System | EC CERTIFICATE No.: EC Certificate Expiration Date: |
| <input checked="" type="checkbox"/> ANNEX I & II+III | N/A |



**Common Specifications (CS):**

| Number: | Title: | Full or Partial Application: |
|---------------|---------------|------------------------------|
| Not Available | Not Available | Not Available |

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 |
| Place of Issue: | Sparks, Maryland, USA |
| Date of Issue: | 23-Mar-2022 |
| Signature: | <div><div>DocuSigned by:</div><div></div><div> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 23-Mar-2022 6:47:10 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div></div> |

DECLARATION OF CONFORMITY Revision History:

| Version: | Detailed Change Description: |
|----------|------------------------------|
| 01 | Initial version |