



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: | Catalog Number | Product Trade Name | |
| | 445923 | BD BACTECT™ MicroMGIT™ Reader | |
| | 441049 | BD BACTECT™ MicroMGIT Calibration Vial | |
| Basic UDI-DI: | Catalog Number | Product Trade Name | Basic UDI-DI |
| | 445923 | BD BACTECT™ MicroMGIT™ Reader | 038290OTKMMWWSNA |
| | 441049 | BD BACTECT™ MicroMGIT Calibration Vial | 038290PSTXICFCP7 |
| Risk Class and Rule: | Class A, Rule 5 (b) | | |
| Intended Purpose: | Catalog Number | Product Trade Name | Intended Purpose |
| | 445923 | BD BACTECT™ MicroMGIT™ Reader | The BD BACTECT™ MicroMGIT™ Reader is an <i>in vitro</i> diagnostic instrument intended to be used with the BD BBL™ MGIT™ 4 mL tubes for the detection and recovery of mycobacteria from clinical specimens (except blood and urine). The device aids in the diagnosis of disease caused by pathogenic microorganisms. It provides qualitative test results using a manual procedure. |
| | 441049 | BD BACTECT™ MicroMGIT Calibration Vial | |

**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.
- Directive 2011/65/EU 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:

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|--|--|
| <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 Specification have not been issued for these products.

Devices Covered by this DoC:

| SKU# | Device Name | Device Class |
|--------|--|--------------|
| 445923 | BD BACTEC™ MicroMGIT™ Reader | Class A |
| 441049 | BD BACTEC™ MicroMGIT Calibration Vial ^a | Class A |

^a Product is not in scope for RoHS Directive 2011/65/EU



| 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: | 15-Nov-2022 |
| Signature: | <div>DocuSigned by: <i>Anne Zavertnik</i>  Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 15-Nov-2022 6:07:58 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div> |

DECLARATION OF CONFORMITY Revision History:

| Version: | Detailed Change Description: |
|----------|---|
| 01 | Initial release |
| 02 | Revision 04 Template change. Updated Conformity Assessment Route, Common specifications table left as blank and formatting changes. |