

**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 | |
| | 256066 | BD Veritor™ Plus Analyzer System and Software | |
| | 445010 | BD Veritor™ InfoWiFi Module | |
| Basic UDI-DI: | Catalog Number | Product Trade name | Basic UDI |
| | 256066 | BD Veritor™ Plus Analyzer System and Software | 038290ELAGYZIN7F |
| | 445010 | BD Veritor™ InfoWiFi Module | 038290KLOTORNEHM |
| Risk Class and Rule : | Catalog Number | Product Trade name | Risk Class & Rules |
| | 256066 | BD Veritor™ Plus Analyzer System and Software | Class A, Rule 4(b) and 5(b) |
| | 445010 | BD Veritor™ InfoWiFi Module | Class A, Rule 5(a) |
| Intended Purpose: | Catalog Number | Product Trade name | Intended Purpose |
| | 256066 | BD Veritor™ Plus Analyzer System and Software | |

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|--|--|-----------------------------|--|
| | 445010 | BD Veritor™ InfoWiFi Module | The BD Veritor™ Plus Analyzer is for use with BD Veritor™ System Test Devices. The BD Veritor Plus Analyzer is an automated instrument intended to measure reflected energy under controlled conditions. |
| Notified Body: | Not applicable, devices self-certified | | |
| <p>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):</p> <ul style="list-style-type: none">• Regulation (EU) 2017/746 on <i>In vitro</i> 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:

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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 specifications have not been issued for these products.

Devices Covered by this DoC:



| SKU# | Device Name | Device Class |
|--------|---|--------------|
| 256066 | BD Veritor™ Plus Analyzer System and Software | Class A |
| 445010 | BD Veritor™ InfoWiFi Module | 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>DocuSigned by:   Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:36:16 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div> |

DECLARATION OF CONFORMITY Revision History:

| Version: | Detailed Change Description: |
|----------|---|
| 01 | Initial release |
| 02 | Changed to New template CBI-058 FRM24-Revision 04. Catalog No included in Intended Purpose Section. Deleted 'Not Available' in Common Specification table. Risk rules has been removed in Devices Covered by this DoC table Updated "On behalf of" with Legal Manufacturer's name. Formatting changes. |