

**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:	<table><tr><th>Catalog Number</th><th>Product Trade Name</th></tr><tr><td>441916</td><td>BD MAX™ System</td></tr><tr><td>443159</td><td>BD Pre-warm Heater</td></tr><tr><td>443584</td><td>BD MAX™ System Software</td></tr></table>			Catalog Number	Product Trade Name	441916	BD MAX™ System	443159	BD Pre-warm Heater	443584	BD MAX™ System Software				
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	443584	BD MAX™ System Software	kits and reagents, is capable of automated extraction and purification of nucleic acids from multiple specimen types. The BD MAX™ System is also capable of automated amplification and detection of target nucleic acid sequences for use in clinical, industrial, and research settings.
	443159	BD Pre-warm Heater	The BD Pre-warm Heater is intended to pre-warm patient samples according to assay-specific, instrument-defined protocols for use with BD instrument systems.
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:

<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
441916	BD MAX™ System	Class A
443159	BD Pre-warm Heater	Class A
443584	BD MAX™ System Software ^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:	10-Nov-2022
Signature:	<div>DocuSigned by: <i>Anne Zavertnik</i>  Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:32:03 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial Release
02	Converted to New Template CBI-058 FRM24-Revision 04. Updated "On behalf of with Legal Manufacturer's Name. Included Catalog Number and Product Name in Intended Purpose. Formatting Changes.