

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 Name	
	441385	BACTEC™ FX Top	
	441386	BD BACTEC™ FX Bottom	
	441370	BD BACTEC™ Digital Thermometer	
	441398	BD BACTEC™ FX System Software	
Basic UDI-DI:	Catalog Number	Product Name	Basic UDI-DI
	441385	BACTEC™ FX Top	038290MMWGVKYYKYY
	441386	BD BACTEC™ FX Bottom	038290MMWGVKYYKYY
	441370	BD BACTEC™ Digital Thermometer	038290FOSBAJMA72
	441398	BD BACTEC™ FX System Software	038290AFBIPBQPW2
Risk Class and Rule:	Catalog Number	Product Name	Risk Class and Rule
	441385	BACTEC™ FX Top	Class A, Rule 5(b)
	441386	BD BACTEC™ FX Bottom	Class A, Rule 5(b)
	441370	BD BACTEC™ Digital Thermometer	Class A, Rule 5(a)
	441398	BD BACTEC™ FX System Software	Class A, Rule 1.4, 5(b)
BD BACTEC™ FX Top, Class A [Rule 5(b)] BD BACTEC™ FX Bottom, Class A [Rule 5(b)] BD BACTEC™ Digital Thermometer, Class A [Rule 5(a)] BD BACTEC™ FX System Software, Class A [Rule 1.4, 5(b)]			



Intended Purpose:	<p>The BD BACTEC™ FX is designed for the rapid detection of bacteria and fungi in clinical specimens, blood, and blood products. Samples are drawn from patients or bagged blood/blood products and injected directly into BD BACTEC™ Culture Vials, which are placed into the instrument for incubation and testing.</p> <p>Additional information</p> <p>The BD BACTEC™ FX is automated and provides qualitative results.</p>
Notified Body:	Not applicable, device self-certified
<p>We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product meet the provisions of the following Directives/ Regulation:</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:
Not available	Not available	Not available


Common Specification have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
441385	BD BACTEC™ FX Top	Class A
441386	BD BACTEC™ FX Bottom	Class A
441370	BD BACTEC™ Digital Thermometer	Class A
441398	BD BACTEC™ FX System Software ^a	Class A

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



Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
Place of Issue:	Sparks, MD, USA
Date of Issue:	23-Mar-2022
Signature:	<p>DocuSigned by:</p> <p><i>Anne Zavertnik</i></p> <p> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 23-Mar-2022 6:48:25 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</p>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Removed WEEE Directive as it is not a CE-marking regulation. Added footnote to clarify that the RoHS directive applies to the instruments only. Minor formatting changes.