



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

	441370	BD BACTEC™ Digital Thermometer	Class A, Rule 5(a)
	441398	BD BACTEC™ FX System Software	Class A, Rule 1.4, 5(b)
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	441385	BACTEC™ FX Top	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. Additional information The BD BACTEC™ FX is automated and provides qualitative results.
	441386	BD BACTEC™ FX Bottom	
	441370	BD BACTEC™ Digital Thermometer	
	441398	BD BACTEC™ FX System Software	
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 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

☒ 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
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

^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 11:36:55 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

**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.
03	Revision 04 Template change, common specifications table left blank and formatting changes.