



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	
	442296	BD BACTEC™ FX40	
	442391	BD BACTEC™ FX40 System Software	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	442296	BD BACTEC™ FX40	038290WAUCLFLID2
	442391	BD BACTEC™ FX40 System Software	038290DEJOCPHN33
Risk Class and Rule:	Catalog Number	Product Trade Name	Risk Class and Rule
	442296	BD BACTEC™ FX40	Class A, Rule 5 (b)
	442391	BD BACTEC™ FX40 System Software	Class A, Rule 1.4 & 5 (b)
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	442296	BD BACTEC™ FX40	The BD BACTEC™ FX40 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.
	442391	BD BACTEC™ FX40 System Software	



			Additional information The BD BACTEC™ FX40 is automated and provides qualitative results.
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): <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
<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 product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
442296	BD BACTEC™ FX40	Class A
442391	BD BACTEC™ FX40 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:   Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:25:56 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Updated to remove 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. Catalog no., Product trade name column included in intended purpose section. Common specifications table left as blank and formatting changes.