

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:	BD BACTEC™ FOS™ Culture Supplement Kit
Basic UDI-DI:	038290QASSNKWSH2
Risk Class and Rule:	Class A, Rule 5 (a)
Intended Purpose:	BD BACTEC FOS Culture Supplement Kit is a fastidious organism supplement and growth enhancer. FOS is provided in a lyophilized form along with a special FOS Reconstituting Fluid (FOS RF) for use with BD BACTEC culture media to enhance the growth of fastidious organisms, such as <i>Haemophilus</i> and <i>Neisseria</i> . Principal use is in conjunction with BD BACTEC blood culture media and the BD BACTEC instruments.
Notified Body:	Not applicable, Device(s) 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. 	

Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
<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 Specifications have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
442153	BD BACTEC™ FOS™ Culture Supplement Kit	Class A

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
Place of Issue:	Sparks, MD, USA
Date of Issue:	29-Apr-2022
Signature:	<p>DocuSigned by:</p>  <p>Anne Zavertnik</p> <p>Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 29-Apr-2022 5:10:36 PM BST DC6A638A32E64A8A91F9D8DE330F0415</p>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release