

## EU DECLARATION OF CONFORMITY (DoC)

<b>Manufacturer:</b>	Becton, Dickinson, and Company 7 Loveton Circle Sparks, Maryland 21152, USA
<b>Manufacturer SRN:</b>	US-MF-000018910
<b>Authorised Representative:</b>	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland
<b>Authorised Representative SRN:</b>	IE-AR-000007610
<b>Product:</b>	BD BACTEC™ FOS™ Culture Supplement Kit
<b>Basic UDI-DI:</b>	038290QASSNKWSH2
<b>Risk Class and Rule:</b>	Class A, Rule 5 (a)
<b>Intended Purpose:</b>	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.
<b>Notified Body:</b>	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"> <li>Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices.</li> </ul>	

### 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:	<div><div>DocuSigned by:</div><div>Anne Zavertnik</div><div> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 29-Apr-2022   5:10:36 PM BST DC6A638A32E64A8A91F9D8DE330F0415</div></div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial release