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**: 442153 **Product Trade Name**: BD BACTEC™ FOS™ Culture Supplement Kit
Basic UDI-DI:	**Catalog Number**: 442153 **Product Trade Name**: BD BACTEC™ FOS™ Culture Supplement Kit **Basic UDI-DI**: 038290QASSNKWSH2
Risk Class and Rule :	Class A, Rule 5 (a)
Intended Purpose:	**Catalog Number**: 442153 **Product Trade Name**: BD BACTEC™ FOS™ Culture Supplement Kit **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 *Haemophilus* and *Neisseria*. Principal use is in conjunction with BD BACTEC blood culture media and the BD BACTEC instruments.
Notified Body:	Not applicable, Device 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):

- Regulation (EU) 2017/746 on *In vitro* Diagnostic Medical Devices.

Conformity Assessment Route:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ 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 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
On behalf of:	Becton, Dickinson and Company
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	DocuSigned by: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 | 11:25:41 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template change, updated details in Product, Basic UDI-DI and Intended Purpose to tabular format, removed not available from common specifications table and formatting changes were made.