



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 BBL™ Seven H11 Agar (Deep Fill), (Cat. No. 221870)
Basic UDI-DI:	038290GSRYBJRHJD
Risk Class and Rule:	Class A, Rule 5(a)
Intended Purpose:	BD BBL™ Seven H11 Agar is used in qualitative procedures for the isolation and cultivation of mycobacteria. The plates are deep-filled to reduce the effects of drying during prolonged incubation.
Notified Body:	Not applicable, device self-certified
We, as the manufacturer of the device take sole responsibility for and hereby declare that the above-mentioned product meets the provisions of the following Directives/ Regulation: <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.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: IVDR 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:
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
221870	BD BBL™ Seven H11 Agar (Deep Fill)	Class A, Rule 5(a)

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-May-2022
Signature:	<div><div>DocuSigned by:</div><div>Anne Zavertnik</div><div><div></div><div>Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-May-2022 6:23:50 PM BST DC6A638A32E64A8A91F9D8DE330F0415</div></div></div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release