



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	
	220908	BD BBL™ Lowenstein-Jensen Medium Slants	
	220909	BD BBL™ Lowenstein-Jensen Medium Slants	
	221116	BD BBL™ Lowenstein-Jensen Medium Mycoflask	
	221832	BD BBL™ Middlebrook 7H9 Broth with Glycerol	
	220959	BD BBL™ Middlebrook and Cohn 7H10 Agar Slants	
	221392	BD BBL™ Seven H11 Agar Slants	
	220502	BD BBL™ Lowenstein-Jensen Medium + PACT	
	220505	BD BBL™ Stonebrink TB Medium + PACT	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	220908	BD BBL™ Lowenstein-Jensen Medium Slants	038290IDDZHHII6G
	220909	BD BBL™ Lowenstein-Jensen Medium Slants	
	221116	BD BBL™ Lowenstein-Jensen Medium Mycoflask	038290IHZKQBLEDF
	221832	BD BBL™ Middlebrook 7H9 Broth with Glycerol	038290IERZWDZOHB
	220959	BD BBL™ Middlebrook and Cohn 7H10 Agar Slants	038290IFBVUULUB9
	221392	BD BBL™ Seven H11 Agar Slants	038290IFVOABNO9F
	220502	BD BBL™ Lowenstein-Jensen Medium + PACT	038290IGHHFAJDZN
	220505	BD BBL™ Stonebrink TB Medium + PACT	038290IGTBUGBU94
Risk Class and Rule :	Class A, Rule 5		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose

	220908	• BD BBL Lowenstein-Jensen Medium Slants • BD BBL Lowenstein-Jensen Medium Mycoflask	BD BBL Lowenstein-Jensen Medium and BD BBL Lowenstein-Jensen Medium Mycoflask are used for the cultivation of <i>Mycobacterium tuberculosis</i> and other mycobacterial species.
	220909	• BD BBL Middlebrook 7H9 Broth with Glycerol	BD BBL Middlebrook 7H9 Broth with Glycerol is a supplemented medium which supports the growth of mycobacteria, including <i>M. tuberculosis</i> . It is used primarily for growth of pure cultures of mycobacteria in laboratory studies.
	221116	• BD BBL Middlebrook and Cohn 7H10 Agar Slants	BD BBL Middlebrook and Cohn 7H10 Agar is used in qualitative procedures for the isolation and cultivation of mycobacteria.
	221832	• BD BBL Seven H11 Agar Slants	Seven H11 Agar is used in qualitative procedures for the isolation and cultivation of mycobacteria.
	220959	• BD BBL Lowenstein-Jensen Medium + PACT	BBL Lowenstein-Jensen Medium + PACT is intended for the cultivation of <i>Mycobacterium tuberculosis</i> and other mycobacterial species.
	221392	• BD BBL Stonebrink TB Medium + PACT	BD BBL Stonebrink TB Medium + PACT is intended for the cultivation of <i>Mycobacterium tuberculosis</i> and other mycobacterial species from specimens containing mixed flora.
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):			
• Regulation (EU) 2017/746 on <i>In vitro</i> 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
220908	BD BBL™ Lowenstein-Jensen Medium Slants	Class A
220909	BD BBL™ Lowenstein-Jensen Medium Slants	
221116	BD BBL™ Lowenstein-Jensen Medium Mycoflask	
221832	BD BBL™ Middlebrook 7H9 Broth with Glycerol	
220959	BD BBL™ Middlebrook and Cohn 7H10 Agar Slants	
221392	BD BBL™ Seven H11 Agar Slants	
220502	BD BBL™ Lowenstein-Jensen Medium + PACT	
220505	BD BBL™ Stonebrink TB Medium + PACT	

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: <i>Anne Zavertnik</i>  Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:32:40 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template Change. Catalog No. Product trade name column included in Intended Purpose section. Common specification table left blank. Formatting changes were made