

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	
	221291	BD BBL™ Trypticase™ Soy Agar with 5% Sheep Blood (TSA II) and BD BBL™ MacConkey II Agar - I Plate™	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	221291	BD BBL™ Trypticase™ Soy Agar with 5% Sheep Blood (TSA II) and BD BBL™ MacConkey II Agar - I Plate™	038290GGROVWVRFY
Risk Class and Rule :	Class A, Rule 5(a)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	221291	BD BBL™ Trypticase™ Soy Agar with 5% Sheep Blood (TSA II) and BD BBL™ MacConkey II Agar - I Plate™	<p>BD BBL Trypticase Soy Agar with 5% Sheep Blood is used for cultivating fastidious microorganisms and for the visualization of hemolytic reactions produced by many bacterial species.</p> <p>BD BBL MacConkey II Agar is a selective and differential medium for the detection of coliform organisms and enteric pathogens.</p>



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):	
<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.: 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:

Common specifications have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
221291	BD BBL™ Trypticase™ Soy Agar with 5% Sheep Blood (TSA II) and BD BBL™ MacConkey II Agar - I Plate™	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:	<div>DocuSigned by:   Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:35:03 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

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 rule from Devices covered by this DoC table, removed not available from common specifications table and formatting changes.