

EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton Dickinson GmbH Tullastrasse 8 – 12 69126 Heidelberg, Germany		
Manufacturer SRN:	DE-MF-000018170		
Authorised Representative:	Not applicable		
Authorised Representative SRN:	Not applicable		
Product:	Catalog Number	Product Trade Name	
	254005	BD Columbia Agar with 5% Sheep Blood	
	254071		
	254051	BD Trypticase™ Soy Agar	
	254086		
	254097	BD Columbia III Agar with 5% Sheep Blood	
	254098		
	212099	BD Trypticase™ Soy Agar II with 5% Horse Blood	
	254053	BD Trypticase™ Soy Agar II with 5% Sheep Blood	
	254087		
	256006	BD Columbia Agar with 5% Horse Blood	
	257836		
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	254005	BD Columbia Agar with 5% Sheep Blood	038290EMEYKDIT9N
	254071		038290EMEYKDIT9N
	254051	BD Trypticase Soy Agar	038290ENCGDNLB2D
	254086		038290ENCGDNLB2D
	254097	BD Columbia III Agar with 5% Sheep Blood	038290EREJHLPZ8S
	254098		038290EREJHLPZ8S
	212099	BD Trypticase Soy Agar II with 5% Horse Blood	038290ELAYKLG7H
	254053	BD Trypticase Soy Agar II with 5% Sheep Blood	038290ENEZOLWACS
	254087		038290ENEZOLWACS

	256006	BD Columbia Agar with 5% Horse Blood	038290ERYPCOXQJJ
	257836		038290ERYPCOXQJJ
Risk Class and Rule:	Class A, Rule 5(a)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	254005	BD Columbia Agar with 5% Sheep Blood	BD Columbia Agar with 5% Sheep Blood is a highly nutritious general purpose medium for the isolation and cultivation of nonfastidious and fastidious microorganisms from clinical specimens.
	254071		
	254051	BD Trypticase™ Soy Agar	BD Trypticase Soy Agar is a general purpose medium which supports the growth of nonfastidious as well as moderately fastidious microorganisms. It is not recommended to be used for the primary isolation of microorganisms from clinical specimens but may be used for subcultivating bacterial strains isolated from clinical specimens to obtain pure cultures and for further differentiation and identification.
	254086		
	254097	BD Columbia III Agar with 5% Sheep Blood	BD Columbia III Agar with 5% Sheep Blood is a highly nutritious general purpose medium for the isolation and cultivation of nonfastidious and fastidious microorganisms from clinical specimens
	254098		
	212099	BD Trypticase™ Soy Agar II with 5% Horse Blood	BD Trypticase™ Soy Agar II With 5% Horse Blood is a nutritious general purpose medium for the isolation and cultivation of nonfastidious and fastidious microorganisms from a variety of clinical specimens and for the indication of hemolytic reactions.
	254053	BD Trypticase™ Soy Agar II with 5% Sheep Blood	BD Trypticase™ Soy Agar II with 5% Sheep Blood is a nutritious general purpose medium for the isolation and cultivation of nonfastidious and fastidious microorganisms from clinical specimens and the indication of hemolytic reactions.
	254087		
	256006	BD Columbia Agar with 5% Horse Blood	Columbia Agar with 5% Horse Blood is a highly nutritious general purpose medium for the isolation and cultivation of nonfastidious and fastidious microorganisms from clinical specimens.
	257836		
Notified Body:	Not applicable, devices 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:

- Regulation (EU) 2017/746 on *In vitro* 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:
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
254005	BD Columbia Agar with 5% Sheep Blood	Class A
254071		Class A
254051	BD Trypticase™ Soy Agar	Class A
254086		Class A
254097	BD Columbia III Agar with 5% Sheep Blood	Class A
254098		Class A
212099	BD Trypticase™ Soy Agar II with 5% Horse Blood	Class A
254053	BD Trypticase™ Soy Agar II with 5% Sheep Blood	Class A
254087		Class A
256006	BD Columbia Agar with 5% Horse Blood	Class A
257836		Class 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: <i>Anne Zavertnik</i></div><div> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-May-2022 6:25:04 PM BST DC6A638A32E64A8A91F9D8DE330F0415</div></div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release