

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
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	BBD 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(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:

<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 these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
254005	BD Columbia Agar with 5% Sheep Blood	Class A
254071	BD Columbia Agar with 5% Sheep Blood	Class A
254051	BD Trypticase™ Soy Agar	Class A
254086	BD Trypticase™ Soy Agar	Class A
254097	BD Columbia III Agar with 5% Sheep Blood	Class A
254098	BD Columbia III Agar with 5% Sheep Blood	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	BD Trypticase™ Soy Agar II with 5% Sheep Blood	Class A
256006	BD Columbia Agar with 5% Horse Blood	Class A
257836	BD Columbia Agar with 5% Horse Blood	Class A

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	Becton Dickinson GmbH



Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	<div><div></div><div> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:35:58 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div></div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial Release
02	Revision 04 Template change, removed not available from common specifications table and formatting changes