

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	
	254060	BD Chocolate Agar (GC II Agar with BD IsoVitaleX™)	
	254089		
	257011	BD Chocolate Agar (Blood Agar No. 2 Base)	
	257456		
	255003	BD Brain Heart Infusion (BHI) Agar	
	255027	BD Brucella Agar with 5% Horse Blood	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	254060	BD Chocolate Agar (GC II Agar with BD IsoVitaleX™)	038290CEEPSSPH55
	254089		
	257011	BD Chocolate Agar (Blood Agar No. 2 Base)	038290CJYQWHOTG3
	257456		
	255003	BD Brain Heart Infusion (BHI) Agar	038290CFJEZPQS5R
	255027	BD Brucella Agar with 5% Horse Blood	038290CHUAFBWQ3S
Risk Class and Rule :	Class A, Rule 5(a)		

Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	254060	BD Chocolate Agar (GC II Agar with BD IsoVitaleX™) and Chocolate Agar (Blood Agar No. 2 Base)	BD Chocolate Agar (GC II Agar with BD IsoVitaleX™) and BD Chocolate Agar (Blood Agar No. 2 Base) are nonselective media for the isolation and cultivation of fastidious microorganisms, especially <i>Neisseria</i> and <i>Haemophilus</i> species, from a variety of clinical specimens.
	254089		
	257011		
	257456		
	255003	BD Brain Heart Infusion (BHI) Agar	BD Brain Heart Infusion (BHI) Agar is a general purpose medium suitable for the cultivation of a wide variety of organism types, including bacteria, yeasts, and filamentous fungi from clinical specimens.
255027	BD Brucella Agar with 5% Horse Blood	BD Brucella Agar with 5% Horse Blood is used for the isolation and growth of fastidious and nonfastidious bacterial species, including Brucella, from clinical specimens.	
Notified Body:	Not applicable, devices self-certified		
<p>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):</p> <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 these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
254060	BD Chocolate Agar (GC II Agar with BD IsoVitaleX™)	Class A
254089	BD Chocolate Agar (GC II Agar with BD IsoVitaleX™)	Class A
257011	BD Chocolate Agar (Blood Agar No. 2 Base)	Class A
257456	BD Chocolate Agar (Blood Agar No. 2 Base)	Class A
255003	BD Brain Heart Infusion (BHI) Agar	Class A
255027	BD Brucella 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>DocuSigned by: <i>Anne Zavertnik</i>  Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:32:54 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template change, removal of product family name and addition of catalog numbers to the table, removed not available from common specifications table and formatting changes