

## EU DECLARATION OF CONFORMITY (DoC)

<b>Manufacturer:</b>	Becton Dickinson GmbH Tullastrasse 8 – 12 69126 Heidelberg, Germany		
<b>Manufacturer SRN:</b>	DE-MF-000018170		
<b>Authorised Representative:</b>	Not applicable		
<b>Authorised Representative SRN:</b>	Not applicable		
<b>Product:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	
	254001	BD Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood	
	254069		
	254403	BD Campylobacter Bloodfree Selective Medium	
	254095		
	254464	BD Campylobacter Agar (Skirrow)	
	256058	BD Campylobacter Agar (Butzler)	
<b>Basic UDI-DI:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	<b>Basic UDI-DI</b>
	254001	BD Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood	038290AJTTLWRMDN
	254069		
	254403	BD Campylobacter Bloodfree Selective Medium	038290ANWVVEOJGL
	254095		
	254464	BD Campylobacter Agar (Skirrow)	038290AUJZRMUTHY
	256058	BD Campylobacter Agar (Butzler)	038290AXLIMMNWCY
<b>Risk Class and Rule :</b>	Class A, Rule 5(a)		
<b>Intended Purpose:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	<b>Intended Purpose</b>
	254001	BD Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood	BD Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood is a selective medium for the primary isolation of <i>Campylobacter jejuni</i> and other cephalothin resistant <i>Campylobacter species</i> from stool specimens.
	254069		
	254403		

	254095	BD Campylobacter Bloodfree Selective Medium	BD Campylobacter Bloodfree Selective Medium is a selective medium for the isolation of <i>Campylobacter</i> species from human fecal specimens.
	254464	BD Campylobacter Agar (Skirrow)	BD Campylobacter Agar (Butzler) and BD Campylobacter Agar (Skirrow) are selective media for the isolation of <i>Campylobacter</i> species from clinical specimens.
	256058	BD Campylobacter Agar (Butzler)	
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):			
<ul style="list-style-type: none"><li>Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices.</li></ul>			

### 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
254001	BD Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood	Class A
254069	BD Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood	Class A
254403	BD Campylobacter Bloodfree Selective Medium	Class A
254095	BD Campylobacter Bloodfree Selective Medium	Class A
254464	BD Campylobacter Agar (Skirrow)	Class A



256058	BD Campylobacter Agar (Butzler)	Class A
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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:   Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022   11:27:20 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

## DECLARATION OF CONFORMITY Revision History:

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