

## 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>	
	254003	BD CLED Agar	
	254070		
	255529	BD CLED Agar (Bevis)	
	257286	BD MacConkey Agar without Salt	
	257562	BD CLED Agar / MacConkey II Agar (Biplate)	
<b>Basic UDI-DI:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	<b>Basic UDI-DI</b>
	254003	BD CLED Agar	038290BBGPYQXX6H
	254070		038290BBGPYQXX6H
	255529	BD CLED Agar (Bevis)	038290BBUOHVBZ6Y
	257286	BD MacConkey Agar without Salt	038290BNLRODAC7W
	257562	BD CLED Agar / MacConkey II Agar (Biplate)	038290BQATVKQD9W
<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>
	254003	BD CLED Agar	BD CLED Agar (Cystine-Lactose-Electrolyte-Deficient Agar) is a differential culture medium for use in isolating and enumerating bacteria from urine. It supports the growth of urinary pathogens and contaminants but prevents undue swarming of <i>Proteus</i> species due to its lack of electrolytes.
	254070		
	255529	BD CLED Agar (Bevis)	BD CLED Agar (Bevis) is a modified CLED (Cystine-Lactose-Electrolyte-Deficient) Agar. It is a differential culture

			medium for use in isolating and enumerating bacteria in urine.
	257286	BD MacConkey Agar without Salt	BD MacConkey Agar without Salt is a differential medium for the isolation of <i>Enterobacteriaceae</i> , staphylococci, and enterococci from clinical specimens such as urine.
	257562	BD CLED Agar / MacConkey II Agar (Biplate)	BD CLED Agar / MacConkey II Agar (Biplate) is used for microbiological urine analysis. CLED Agar is a differential culture medium for use in isolating and enumerating bacteria in urine. MacConkey II Agar is a selective and differential medium for the isolation and differentiation of <i>Enterobacteriaceae</i> and a variety of other gram-negative rods from clinical and non-clinical specimens.
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
254003	BD CLED Agar	Class A
254070	BD CLED Agar	Class A
255529	BD CLED Agar (Bevis)	Class A
257286	BD MacConkey Agar without Salt	Class A
257562	BD CLED Agar / MacConkey II Agar (Biplate)	Class A

Authorised Signatory:	
<b>Name &amp; Title:</b>	Anne Zavertnik, Vice President, Regulatory Affairs
<b>On behalf of:</b>	Becton Dickinson GmbH
<b>Place of Issue:</b>	Sparks, MD, USA
<b>Date of Issue:</b>	10-Nov-2022
<b>Signature:</b>	<p>DocuSigned by:</p> <p><i>Anne Zavertnik</i></p> <p> Signer Name: Anne Zavertnik  Signing Reason: I approve this document  Signing Time: 10-Nov-2022   11:36:09 PM GMT  DC6A638A32E64A8A91F9D8DE330F0415</p>

## 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