

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	
	254429	BD Dermatophyte Agar	
	254413	BD Kimmig Fungal Agar	
	254417	BD Mycosel™ Agar	
	255504	BD Sabouraud Agar with Chloramphenicol and Cycloheximide	
	254041	BD Sabouraud Agar with Gentamicin and Chloramphenicol	
	254096		
	254091	BD Sabouraud Agar with Chloramphenicol	
	254039		
	254083	BD Sabouraud Glucose Agar	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	254429	BD Dermatophyte Agar	038290UXJPXKTLUE
	254413	BD Kimmig Fungal Agar	038290TPNJKEIVJX
	254417	BD Mycosel™ Agar	038290UQJUNXUIS6
	255504	BD Sabouraud Agar with Chloramphenicol and Cycloheximide	038290AJEWQOAS78
	254041	BD Sabouraud Agar with Gentamicin and Chloramphenicol	038290OYZZSIDXZ6
	254096		
	254091	BD Sabouraud Agar with Chloramphenicol	038290TPATVVSXGN6

	254039	BD Sabouraud	038290OTSLVUTGRT
	254083	Glucose Agar	
Risk Class and Rule :			
Class A, Rule 5 (a)			
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	254429	BD Dermatophyte Agar	BD Dermatophyte Agar is a selective medium for the isolation of pathogenic fungi from cutaneous sources such as skin, hair, and nails.
	254413	BD Kimmig Fungal Agar	BD Kimmig Fungal Agar is used for the isolation and cultivation of fungi from clinical specimens.
	254417	BD Mycosel™ Agar	BD Mycosel™ Agar and BD Sabouraud Agar with Chloramphenicol and Cycloheximide are highly selective media for the isolation of pathogenic fungi from materials having a large flora of other fungi and bacteria. They are not general-purpose media for the isolation of all fungi (including molds and saprophytic yeasts).
	255504	BD Sabouraud Agar with Chloramphenicol and Cycloheximide	
	254041	BD Sabouraud Agar with Gentamicin and Chloramphenicol	BD Sabouraud Glucose Agar is used for the isolation and cultivation of fungi (yeasts, molds, and dermatophytes) from clinical specimens. BD Sabouraud Agar with Chloramphenicol and BD Sabouraud Agar with Gentamicin and Chloramphenicol are selective media for the isolation of fungi from clinical specimens.
	254096		
	254091	BD Sabouraud Agar with Chloramphenicol	
	254039	BD Sabouraud Glucose Agar	
	254083		
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
254429	BD Dermatophyte Agar	Class A
254413	BD Kimmig Fungal Agar	Class A
254417	BD Mycosel™ Agar	Class A
255504	BD Sabouraud Agar with Chloramphenicol and Cycloheximide	Class A
254041	BD Sabouraud Agar with Gentamicin and Chloramphenicol	Class A
254096	BD Sabouraud Agar with Gentamicin and Chloramphenicol	Class A
254091	BD Sabouraud Agar with Chloramphenicol	Class A
254039	BD Sabouraud Glucose Agar	Class A
254083	BD Sabouraud Glucose Agar	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:	02-Oct-2023
Signature:	<p>DocuSigned by:</p> <p><i>Anne Zavertnik</i></p> <p> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 02-Oct-2023 1:14:49 PM BST 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
03	Deletion of Cat. No. 254451, due to discontinuation, see CC-2023-326