



EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152, USA	
Manufacturer SRN:	US-MF-000018910	
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26, Ireland	
Authorised Representative SRN:	IE-AR-000007610	
Product:	Catalog Number	Product Trade Name
	221328	BD BBL™ OF Medium with Dextrose
	221677	BD BBL™ Phenol Red Broth with Dextrose and Durham Tube
	221383	BD BBL™ Enterococcosel™ Broth
	221409	BD BBL™ Bile Esculin Agar Slants, 10 pack 6.8 mL
	221410	BD BBL™ Bile Esculin Agar Slants, 100 pack 6.8 mL
	220897	BD BBL™ Kligler Iron Agar Slants
	220953	BD BBL™ Lysine Iron Agar Slants
	221509	BD BBL™ Motility Test Medium
	221517	BD BBL™ Motility Indole Ornithine (MIO) Medium, 5 mL of 10 size K tubes
	221518	BD BBL™ Motility Indole Ornithine (MIO) Medium, 5 mL of 100 size K tubes
	221632	BD BBL™ CTA Medium™
	221661	BD BBL™ Moeller Decarboxylase Broth with Lysine
	221729	BD BBL™ GN Broth, 10 pack 8 mL
	221730	BD BBL™ GN Broth, 100 pack 8 mL
	221020	BD BBL™ Selenite-F, 8 mL of 10 size K tubes
	221021	BD BBL™ Selenite-F, 8 mL of 100 size K tubes
	221026	BD BBL™ Simmons Citrate Agar Slants
	221010	BD BBL™ SIM Medium
	221039	BD BBL™ TSI Agar™ Slants (Triple Sugar Iron Agar), 100 size K tubes
	221096	BD BBL™ Urea Agar Slants, 10 size K tubes



	221097	BD BBL™ Urea Agar Slants, 100 size K tubes	
	221100	BD BBL™ Urea Agar Base Concentrate 10X	
	221719	BD BBL™ Urease Test Broth	
	298330	BD BBL™ Rapid Urea Broth	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	221328	BD BBL™ OF Medium with Dextrose	038290LIOCZBPJB7
	221677	BD BBL™ Phenol Red Broth with Dextrose and Durham Tube	038290LNLQQNWJHZ
	221383	BD BBL™ Enterococcosel™ Broth	038290LQCQRYJUHC
	221409	BD BBL™ Bile Esculin Agar Slants, 10 pack 6.8 mL	038290LSHAKADD82
	221410	BD BBL™ Bile Esculin Agar Slants, 100 pack 6.8 mL	038290LSHAKADD82
	220897	BD BBL™ Kligler Iron Agar Slants	038290LSRNRJNNM3
	220953	BD BBL™ Lysine Iron Agar Slants	038290LVMUWLVIQX
	221509	BD BBL™ Motility Test Medium	038290MBSSIJDXXG
	221517	BD BBL™ Motility Indole Ornithine (MIO) Medium, 5 mL of 10 size K tubes	038290MBZQCGRBCS
	221518	BD BBL™ Motility Indole Ornithine (MIO) Medium, 5 mL of 100 size K tubes	038290MBZQCGRBCS
	221632	BD BBL™ CTA Medium™	038290MCFFNRRR6J
	221661	BD BBL™ Moeller Decarboxylase Broth with Lysine	038290MCWMKWWEFM
	221729	BD BBL™ GN Broth, 10 pack 8 mL	038290MDXGKYWCEP
	221730	BD BBL™ GN Broth, 100 pack 8 mL	038290MDXGKYWCEP
	221020	BD BBL™ Selenite-F, 8 mL of 10 size K tubes	038290MGDHEVNM6H

	221021	BD BBL™ Selenite-F, 8 mL of 100 size K tubes	038290MGDHEVNM6H
	221026	BD BBL™ Simmons Citrate Agar Slants	038290MGKSZQDEFH
	221010	BD BBL™ SIM Medium	038290MKNLQILEDY
	221039	BD BBL™ TSI Agar™ Slants (Triple Sugar Iron Agar), 100 size K tubes	038290MLJTXHYHLJ
	221096	BD BBL™ Urea Agar Slants, 10 size K tubes	038290MNRBGVREE6
	221097	BD BBL™ Urea Agar Slants, 100 size K tubes	038290MNRBGVREE6
	221100	BD BBL™ Urea Agar Base Concentrate 10X	038290MNSQBPXQJZ
	221719	BD BBL™ Urease Test Broth	038290MQKFONEFDM
	298330	BD BBL™ Rapid Urea Broth	038290NESYQVSELK
Risk Class and Rule :	Class A, Rule 5 (a)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	221328	BD BBL™ OF Medium with Dextrose	OF (Oxidation Fermentation) media are used for the determination of oxidative and fermentative metabolism of carbohydrates by gram-negative rods on the basis of acid reaction in either the open or closed system.
	221677	BD BBL™ Phenol Red Broth with Dextrose and Durham Tube	Phenol Red Broth Base and Phenol Red Broth with carbohydrates are used for the determination of fermentation reactions in the differentiation of microorganisms.
	221383	BD BBL™ Enterococcosel Broth	Enterococcosel Broth is recommended for use in the differentiation of Enterococci
	221409	BD BBL™ Bile Esculin Agar Slants	Bile Esculin Agar is used to differentiate enterococci and the <i>Streptococcus bovis</i> group from other streptococci.
	221410		

	220897	BD BBL™ Kligler Iron Agar Slants	Kligler Iron Agar is used for the differentiation of members of the Enterobacteriaceae on the basis of their ability to ferment dextrose and lactose and to produce sulfides.
	220953	BD BBL™ Lysine Iron Agar Slants	Lysine Iron Agar is used for the differentiation of enteric organisms based on their ability to decarboxylate or deaminate lysine and to form hydrogen sulfide.
	221509	BD BBL™ Motility Test Medium	Motility Test Medium is used for the detection of motility of gram-negative enteric bacilli.
	221517	BD BBL™ Motility Indole Ornithine (MIO) Medium,	Motility Indole Ornithine (MIO) Medium is used to demonstrate motility, indole production and ornithine decarboxylase activity for the differentiation of Enterobacteriaceae.
	221518		
	221632	BD BBL™ CTA Medium	CTA Medium is a culture medium for the maintenance of microorganisms. It is also used for the detection of bacterial motility and, with added carbohydrate, for fermentation reactions of fastidious microorganisms, i.e., <i>Neisseria</i> , pneumococci, streptococci and non-spore forming anaerobes.
	221661	BD BBL™ Moeller Decarboxylase Broth with Lysine	BD BBL Moeller Decarboxylase media is used in the biochemical differentiation of gram-negative enteric bacilli based on the production of lysine and ornithine decarboxylase.
	221729	BD BBL™ GN Broth	GN Broth is used for the selective enrichment of <i>Salmonella</i> and <i>Shigella</i> .
	221730		
	221020	BD BBL™ Selenite-F Broth	Selenite-F Broth is used as an enrichment medium for the

	221021		isolation of Salmonella from feces, urine, water, foods and other materials of sanitary importance
	221026	BD BBL™ Simmons Citrate Agar Slants	Simmons Citrate Agar is used for the differentiation of gram-negative bacteria on the basis of citrate utilization.
	221010	BD BBL™ SIM Medium	SIM Medium is used to differentiate enteric bacilli on the basis of sulfide production, indole formation and motility.
	221039	BD BBL™ TSI Agar Slants	TSI Agar is used for the differentiation of gram-negative enteric bacilli based on carbohydrate fermentation and the production of hydrogen sulfide.
	221096	BD BBL™ Urea Agar Slants	Urea Agar is used for the differentiation of organisms, especially the Enterobacteriaceae, on the basis of urease production.
	221097	BD BBL™ Urea Agar Base Concentrate 10X	
	221100		
	221719	BD BBL™ Urease Test Broth	Urease Test Broth is used for the differentiation of organisms, especially the Enterobacteriaceae, on the basis of urease production.
	298330	BD BBL™ Rapid Urea Broth	Rapid Urea Broth is used for the presumptive identification of Helicobacter pylori in gastric antral biopsy 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): Regulation (EU) 2017/746 on <i>In Vitro</i> Diagnostic Medical Devices.			

**Conformity Assessment Route:**

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☒ ANNEX I & II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common Specifications have not been issued for this products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
221328	BD BBL™ OF Medium with Dextrose	Class A
221677	BD BBL™ Phenol Red Broth with Dextrose and Durham Tube	
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298330	BD BBL™ Rapid Urea Broth	

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	Becton, Dickinson and Company
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	DocuSigned by:   Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:27:00 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

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 were made.