

**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
	261191	BD BBL 10% Potassium Hydroxide Reagent Droppers
	261182	BD BBL Acridine Orange Reagent Droppers
	261195	BD BBL Calcofluor White Reagent Droppers
	261183	BD BBL Desoxycholate Reagent Droppers
	261187	BD BBL DMACA Indole Reagent Droppers
	261189	BD BBL Dobell and O'Connor Iodine Stain Droppers
	261190	BD BBL Ferric Chloride Reagent Droppers
	261194	BD BBL India Ink Reagent Droppers
	261185	BD BBL Indole Reagent Droppers
	261188	BD BBL Lactophenol Cotton Blue Stain Droppers
	261204	BD BBL Methylene Blue Loeffler Stain Droppers
	261201	BD BBL Ninhydrin Reagents Droppers
	261197	BD BBL Nitrate A Reagent Droppers
	261198	BD BBL Nitrate B Reagent Droppers
	261181	BD BBL Oxidase Reagent Droppers
	261196	BD BBL PYR Reagent Droppers
	261192	BD BBL Voges-Proskauer A Reagent Droppers
	261193	BD BBL Voges-Proskauer B Reagent Droppers
	261203	BD BBL Catalase Reagent Droppers

Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	261191	BD BBL 10% Potassium Hydroxide Reagent Droppers	038290QBSJSEMFCV
	261182	BD BBL Acridine Orange Reagent Droppers	038290LLTAZPUUHG
	261195	BD BBL Calcofluor White Reagent Droppers	038290UETUFQHPL8
	261183	BD BBL Desoxycholate Reagent Droppers	038290BGJKNBCBYG
	261187	BD BBL DMACA Indole Reagent Droppers	038290QWYDZHXOTZ
	261189	BD BBL Dobell and O'Connor Iodine Stain Droppers	038290ZESDLBKCFD
	261190	BD BBL Ferric Chloride Reagent Droppers	038290BJVRBSYMC8
	261194	BD BBL India Ink Reagent Droppers	038290EDZAIPWL7E
	261185	BD BBL Indole Reagent Droppers	038290AKLYDUGO9P
	261188	BD BBL Lactophenol Cotton Blue Stain Droppers	038290QYVVKZTMZ3
	261204	BD BBL Methylene Blue Loeffler Stain Droppers	038290JPHIZMVEEW
	261201	BD BBL Ninhydrin Reagents Droppers	038290CAGSCXJT2B
	261197	BD BBL Nitrate A Reagent Droppers	038290JPEKPQSXDQ
	261198	BD BBL Nitrate B Reagent Droppers	038290VOLNFBFGHD
	261181	BD BBL Oxidase Reagent Droppers	038290EHIAMACSXM
	261196	BD BBL PYR Reagent Droppers	038290CRSWFBDEDB
	261192	BD BBL Voges-Proskauer A Reagent Droppers	038290COBHWP6T6S
	261193	BD BBL Voges-Proskauer B Reagent Droppers	038290DTDYTLIDEL
	261203	BD BBL Catalase Reagent Droppers	038290PEXCVVFQGU

Risk Class and Rule:	Class A, Rule 5(a)		
Intended Purpose:	Catalog Number	Product Trade name	Intended Purpose
	261191	BD BBL™ 10% Potassium Hydroxide Reagent Droppers	BD BBL™ 10% Potassium Hydroxide Reagent Droppers are intended for use in the examination of direct smears for fungal elements
	261182	BD BBL™ Acridine Orange Reagent Droppers	BD BBL™ Acridine Orange Reagent Droppers are used for fluorescent microscopic detection of microorganisms in direct smears.
	261195	BD BBL™ Calcofluor White Reagent Droppers	BD BBL™ Calcofluor White Reagent Droppers are used in the rapid fluorescent microscopic detection of fungi in direct smears.
	261183	BD BBL™ Desoxycholate Reagent Droppers	BD BBL™ Desoxycholate Reagent Droppers are used for the presumptive differentiation of pneumococci from other gram-positive cocci by the bile solubility test.
	261187	BD BBL™ DMACA Indole Reagent Droppers	For the detection of indole production as an aid in the identification of aerobic, anaerobic, or facultatively anaerobic organisms.
	261189	BD BBL™ Dobell and O'Connor Iodine Stain Droppers	BD BBL™ Dobell and O'Connor Iodine Stain Droppers have a variety of uses as a microbiological stain. Among them are staining the trophozoite, cyst, and egg stages of intestinal parasites.
	261190	BD BBL™ Ferric Chloride Reagent Droppers	BD BBL™ Ferric Chloride Reagent Droppers are intended for use in the differentiation of microorganisms capable of phenylalanine deamination.
	261194	BD BBL™ India Ink Reagent Droppers	BD BBL™ India Ink Reagent Droppers are used to enhance the microscopic detection of <i>Cryptococcus</i> spp. in wet preparations.
	261185	BD BBL™ Indole Reagent Droppers	BD BBL™ Indole Reagent Droppers (modified Kovacs' reagent) are used in determining the ability of bacteria to produce indole by the deamination of tryptophan.
	261188	BD BBL™ Lactophenol Cotton Blue Stain Droppers	BD BBL™ Lactophenol Cotton Blue Stain Droppers are intended for use as a stain in the examination of fungi.

	261204	BD BBL™ Methylene Blue Loeffler Stain Droppers	BD BBL™ Methylene Blue Loeffler Stain Droppers are used for presumptive identification of <i>Corynebacterium diphtheriae</i> and as an adjunct to the Gram stain.
	261201	BD BBL™ Ninhydrin Reagents Droppers	BD BBL™ Ninhydrin Reagent Droppers are used in the determination of the hippurate reaction to aid in the identification of certain bacteria.
	261197	BD BBL™ Nitrate A Reagent Droppers	BD BBL™ Nitrate Reagent A and BD BBL Nitrate Reagent B Droppers are for use in determining the ability of bacteria to reduce nitrate to nitrite or free nitrogen gas.
	261198	BD BBL™ Nitrate B Reagent Droppers	
	261181	BD BBL™ Oxidase Reagent Droppers	BD BBL™ Oxidase Reagent Droppers are used in the Kovacs oxidase test as a qualitative reaction in the identification of nonfermenters and miscellaneous gram-negative bacteria.
	261196	BD BBL™ PYR Reagent Droppers	BD BBL™ PYR Reagent Droppers are used in the rapid presumptive identification of group A β-hemolytic streptococci and group D enterococci.
	261192	BD BBL™ Voges-Proskauer A Reagent Droppers	BD BBL™ Voges-Proskauer Reagent Droppers are intended for use in the Voges-Proskauer test, one of several qualitative tests used to distinguish between members of the Enterobacteriaceae.
	261193	BD BBL™ Voges-Proskauer B Reagent Droppers	
	261203	BD BBL™ Catalase Reagent Droppers	BD BBL™ Catalase Reagent Droppers are used for determining the presence of catalase produced by bacteria.
Notified Body:		Not applicable, device(s) 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:**

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

Common Specifications (CS):

Number:	Title:	Full or Partial Application:
Not Available	Not Available	Not Available

Common Specifications have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
261191	BD BBL™ 10% Potassium Hydroxide Reagent Droppers	Class A
261182	BD BBL™ Acridine Orange Reagent Droppers	Class A
261195	BD BBL™ Calcofluor White Reagent Droppers	Class A
261183	BD BBL™ Desoxycholate Reagent Droppers	Class A
261187	BD BBL™ DMACA Indole Reagent Droppers	Class A
261189	BD BBL™ Dobell and O'Connor Iodine Stain Droppers	Class A
261190	BD BBL™ Ferric Chloride Reagent Droppers	Class A
261194	BD BBL™ India Ink Reagent Droppers	Class A
261185	BD BBL™ Indole Reagent Droppers	Class A
261188	BD BBL™ Lactophenol Cotton Blue Stain Droppers	Class A
261204	BD BBL™ Methylene Blue Loeffler Stain Droppers	Class A
261201	BD BBL™ Ninhydrin Reagents Droppers	Class A
261197	BD BBL™ Nitrate A Reagent Droppers	Class A
261198	BD BBL™ Nitrate B Reagent Droppers	Class A
261181	BD BBL™ Oxidase Reagent Droppers	Class A
261196	BD BBL™ PYR Reagent Droppers	Class A
261192	BD BBL™ Voges-Proskauer A Reagent Droppers	Class A
261193	BD BBL™ Voges-Proskauer B Reagent Droppers	Class A
261203	BD BBL™ Catalase Reagent Droppers	Class A



Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice president, Regulatory Affairs
Place of Issue:	Sparks, MD, USA
Date of Issue:	16-May-2022
Signature:	DocuSigned by:   Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 16-May-2022 2:00:23 PM BST DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Updated with BD BBL Catalase Reagent Droppers details