EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 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
231248	BD BBL™ Taxo™ O-nitrophenyl-B-D-Galactopyranoside 100 µg
231750	BD BBL™ Taxo™ Novobiocin
231562	BD BBL™ Taxo™ Kanamycin 1.0 mg
231651	BD BBL™ Taxo™ Anaerobe Differentiation Discs Set

Basic UDI-DI:

Catalog Number	Product Trade Name	Basic UDI-DI
231248	BD BBL™ Taxo™ O-nitrophenyl-B-D-Galactopyranoside 100 µg	038290HHTYIVDXH2
231750	BD BBL™ Taxo™ Novobiocin	038290HITPBHEKA2
231562	BD BBL™ Taxo™ Kanamycin 1.0 mg	038290HJEQOCCV7D
231651	BD BBL™ Taxo™ Anaerobe Differentiation Discs Set	038290HJFHUWIX9T

Risk Class and Rule : Class A, Rule 5

Intended Purpose:

Catalog Number	Product Trade Name	Intended Purpose
231248	BD BBL™ Taxo™ O-nitrophenyl-B-D-Galactopyranoside 100 µg	BD BBL™ Taxo™ ONPG Discs are used for the detection of lactose fermenters, especially those that do not promptly ferment lactose in some routine identification media such as Triple Sugar Iron Agar (TSI Agar) or Kligler Iron Agar.

	231750	BD BBL™ Taxo™ Novobiocin	BD BBL™ Taxo™ Differentiation Discs Novobiocin are recommended for the differentiation of coagulase-negative staphylococci (e.g., *Staphylococcus saprophyticus*) based on novobiocin resistance.
	231562	BD BBL™ Taxo™ Kanamycin 1.0 mg	These discs are recommended for use in the presumptive identification of gram-negative anaerobic bacilli based on differences in susceptibility to antimicrobial agents. This procedure is not for use for therapeutic purposes.
	231651	BD BBL™ Taxo™ Anaerobe Differentiation Discs Set	These discs are recommended for use in the presumptive identification of gram-negative anaerobic bacilli based on differences in susceptibility to antimicrobial agents. This procedure is not for use for therapeutic purposes.
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:

☐ 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 product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
231248	BD BBL™ Taxo™ ONPG	Class A
231750	BD BBL™ Taxo™ Novobiocin	Class A
231562	BD BBL™ Taxo™ Kanamycin 1.0 mg	Class A
231651	BD BBL™ Taxo™ Anaerobe Differentiation Discs Set	Class A

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: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 | 11:35:24 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template Change. Catalog Number, Product trade name column included in intended purpose section. Common specification table left blank. Formatting changes were made.