

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	
	260457	BD BBL™ Sensi-Disc™ Single Dispenser, 1 Each	
	260459	BD BBL™ Sensi-Disc™ Single Dispenser, 6 Each	
	260661	BD BBL™ Sensi-Disc™ 6-Place Self-Tamping Dispenser	
	260660	BD BBL™ Sensi-Disc™ 8-Place Self-Tamping Dispenser	
	260640	BD BBL™ Sensi-Disc™ 12-Place Self-Tamping Dispenser	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	260457	BD BBL™ Sensi-Disc™ Single Dispenser, 1 Each	038290TQJQCDBTHK
	260459	BD BBL™ Sensi-Disc™ Single Dispenser, 6 Each	038290BDKPIXZR6
	260661	BD BBL™ Sensi-Disc™ 6-Place Self-Tamping Dispenser	038290HXXNADCQJA
	260660	BD BBL™ Sensi-Disc™ 8-Place Self-Tamping Dispenser	038290NCSUZXPFL7
	260640	BD BBL™ Sensi-Disc™ 12-Place Self-Tamping Dispenser	038290YCQVEEXVLF
Risk Class and Rule:	Class A and Rule 5 (b)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	260457	BD BBL™ Sensi-Disc™ Single Dispenser, 1 Each	The BD BBL Sensi-Disc Single Disc Dispenser is recommended for the

	260459	BD BBL™ Sensi-Disc™ Single Dispenser, 6 Each	individual application of cartridged BD BBL brand antimicrobial susceptibility test and biochemical differentiation discs onto the surface of inoculated plated media. The Single Disc Dispenser replaces the manual placement of discs using sterile forceps.
	260661	BD BBL™ Sensi-Disc™ 6-Place Self-Tamping Dispenser	These BD BBL Sensi-Disc self-tamping dispensers accommodate either 6 or 8 cartridges of BD BBL Sensi-Disc susceptibility test discs or BD BBL Taxo anaerobe differentiation discs. They are used to deliver discs onto 100 mm-style Petri dishes when performing disc susceptibility testing or for the presumptive identification of gram-negative anaerobic bacilli.
	260660	BD BBL™ Sensi-Disc™ 8-Place Self-Tamping Dispenser	
	260640	BD BBL™ Sensi-Disc™ 12-Place Self-Tamping Dispenser	The 12-Place BD BBL Sensi-Disc self-tamping dispenser accommodates up to 12 cartridges of BD BBL Sensi-Disc susceptibility test discs. It is used to deliver discs onto 150 mm-style Petri dishes when performing disc susceptibility testing, especially by the standardized method.
Notified Body:		Not applicable, Device 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">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 this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
260457	BD BBL™ Sensi-Disc™ Single Dispenser, 1 Each	Class A
260459	BD BBL™ Sensi-Disc™ Single Dispenser, 6 Each	Class A
260661	BD BBL™ Sensi-Disc™ 6-Place Self-Tamping Dispenser	Class A
260660	BD BBL™ Sensi-Disc™ 8-Place Self-Tamping Dispenser	Class A
260640	BD BBL™ Sensi-Disc™ 12-Place Self-Tamping Dispenser	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:	<div>DocuSigned by:   Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:35:17 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Corrected typo in BUDI of cat # 260459. Minor formatting changes.
03	Revision 04 template change. Common specification table left blank. TM symbols are inserted under product trade name. Formatting changes were made.