



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	
	260683	BD GasPak™ EZ Anaerobe Gas Generating Pouch System with Indicator	
	260684	BD GasPak™ EZ CO ₂ Gas Generating Pouch System	
	260685	BD GasPak™ EZ Campy Gas Generating Pouch System	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	260683	BD GasPak™ EZ Anaerobe Gas Generating Pouch System with Indicator	038290ULDLCKJWDD
	260684	BD GasPak™ EZ CO ₂ Gas Generating Pouch System	038290UUMVDIRQRJ
	260685	BD GasPak™ EZ Campy Gas Generating Pouch System	038290VGHZAJRLT
Risk Class and Rule :	Class A, Rule 5(a)		
Intended Purpose:	The BD GasPak EZ Gas Generating Pouch Systems are single-use systems that produce atmospheres suitable to support the primary isolation and cultivation of anaerobic, microaerophilic, or capnophilic bacteria by use of gas generating sachets inside single-use resealable pouches.		
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):			
<ul style="list-style-type: none">Regulation (EU) 2017/746 on <i>In Vitro</i> 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):

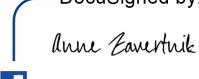
Number:	Title:	Full or Partial Application:
Not Available	Not Available	Not Available

Common Specifications have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
260683	BD GasPak™ EZ Anaerobe Gas Generating Pouch System with Indicator	Class A, Rule 5 (a)
260684	BD GasPak™ EZ CO ₂ Gas Generating Pouch System	Class A, Rule 5 (a)
260685	BD GasPak™ EZ Campy Gas Generating Pouch System	Class A, Rule 5 (a)

Authorised Signatory:

Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-May-2022
Signature:	<p>DocuSigned by:</p> <p></p> <p>Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-May-2022 6:22:53 PM BST DC6A638A32E64A8A91F9D8DE330F0415</p>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial release