



## EU DECLARATION OF CONFORMITY (DoC)

<b>Manufacturer:</b>	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152 USA		
<b>Manufacturer SRN:</b>	US-MF-000018910		
<b>Authorised Representative:</b>	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26, Ireland		
<b>Authorised Representative SRN:</b>	IE-AR-000007610		
<b>Product:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	
	260683	BD GasPak™ EZ Anaerobe Gas Generating Pouch System with Indicator	
	260684	BD GasPak™ EZ CO <sub>2</sub> Gas Generating Pouch System	
	260685	BD GasPak™ EZ Campy Gas Generating Pouch System	
<b>Basic UDI-DI:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	<b>Basic UDI-DI</b>
	260683	BD GasPak™ EZ Anaerobe Gas Generating Pouch System with Indicator	038290ULDLCKJWDD
	260684	BD GasPak™ EZ CO <sub>2</sub> Gas Generating Pouch System	038290UUMVDIRQRJ
	260685	BD GasPak™ EZ Campy Gas Generating Pouch System	038290VGWHZAJRLT
<b>Risk Class and Rule :</b>	Class A, Rule 5(a)		
<b>Intended Purpose:</b>	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.		
<b>Notified Body:</b>	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"><li>Regulation (EU) 2017/746 on <i>In Vitro</i> Diagnostic Medical Devices.</li></ul>			

**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 <sub>2</sub> 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:	<div>DocuSigned by:  Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-May-2022   6:22:53 PM BST DC6A638A32E64A8A91F9D8DE330F0415</div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial release