

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	038290VGWHZAJRLT
Risk Class and Rule :	Class A, Rule 5 (a)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	260683	BD GasPak™ EZ Anaerobe Gas Generating Pouch System with Indicator	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.
	260684	BD GasPak™ EZ CO ₂ Gas Generating Pouch System	
	260685	BD GasPak™ EZ Campy Gas Generating Pouch System	
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:

<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 these product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
260683	BD GasPak™ EZ Anaerobe Gas Generating Pouch System with Indicator	Class A
260684	BD GasPak™ EZ CO ₂ Gas Generating Pouch System	Class A
260685	BD GasPak™ EZ Campy Gas Generating Pouch System	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><div>DocuSigned by:</div><div></div><div> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:31:39 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div></div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template change, updated details in Product, Basic UDI-DI and Intended Purpose to tabular format, removed rule from Devices covered by this DoC table, removed not available from common specifications table and formatting changes were made.