

**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	
	260001	BD GasPak™ EZ Anaerobe Container System Sachets with Indicator	
	260678	BD GasPak™ EZ Anaerobe Container System Sachets	
	260679	BD GasPak™ EZ CO ₂ Container System Sachets	
	260680	BD GasPak™ EZ Campy Container System Sachets	
	260002	BD GasPak™ EZ Small Incubation Container	
	260671	BD GasPak™ EZ Standard Incubation Container	
	260672	BD GasPak™ EZ Large Incubation Container	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	260001	BD GasPak™ EZ Anaerobe Container System Sachets with Indicator	038290SPOLCETBHG
	260678	BD GasPak™ EZ Anaerobe Container System Sachets	038290CLNMTBHH8A
	260679	BD GasPak™ EZ CO ₂ Container System Sachets	038290SVKQNJJOPT
	260680	BD GasPak™ EZ Campy Container System Sachets	038290XQOYJULXW4
	260002	BD GasPak™ EZ Small Incubation Container	038290XUGGGABOHH
	260671	BD GasPak™ EZ Standard Incubation Container	038290XDUXMJFFNJ
	260672	BD GasPak™ EZ Large Incubation Container	038290YSNNNLGYSM
Risk Class and Rule :	Class A, Rule 5 (a)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose



	260001	BD GasPak™ EZ Anaerobe Container System Sachets with Indicator	The BD GasPak EZ Gas Generating Container Systems are multi-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 multi-use incubation containers.
	260678	BD GasPak™ EZ Anaerobe Container System Sachets	
	260679	BD GasPak™ EZ CO ₂ Container System Sachets	
	260680	BD GasPak™ EZ Campy Container System Sachets	
	260002	BD GasPak™ EZ Small Incubation Container	
	260671	BD GasPak™ EZ Standard Incubation Container	
	260672	BD GasPak™ EZ Large Incubation Container	
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 <i>In Vitro</i> 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 products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
260001	BD GasPak™ EZ Anaerobe Container System Sachets with Indicator	Class A



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260671	BD GasPak™ EZ Standard Incubation Container	
260672	BD GasPak™ EZ Large Incubation Container	

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: <i>Anne Zavertnik</i> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:31:32 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

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 not available from common specifications table and Formatting changes were made.