

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	
	261510	BD Bio-Bag™ Type C	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	261510	BD Bio-Bag™ Type C	038290WVMLBFFKME
Risk Class and Rule :	Class A, Rule 5 (a)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	261510	BD Bio-Bag™ Type C	BD Bio-Bag Type C is a disposable environmental system designed to rapidly generate and maintain a carbon dioxide environment for 48 hours. Each system contains a sealable translucent BD Bio-Bag and a CO ₂ Gas Generator.
Notified Body:	Not applicable, Device self-certified		
<p>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):</p> <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:

Common Specifications have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
261510	BD Bio-Bag™ Type C	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 11:26:52 PM GMT DC6A638A32E64A8A91F9D8DE330F0415 </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.