

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 443806	Product Trade Name BD MAX™ STR	
Basic UDI-DI:	Catalog Number 443806	Product Trade Name BD MAX™ STR	Basic UDI-DI 038290CDZXTPZWHH
Risk Class and Rule:	Class A, Rule 5 (a)		
Intended Purpose:	Catalog Number 443806	Product Trade Name BD MAX™ STR	Intended Purpose BD MAX™ STR is a manual specimen processing reagent intended to liquefy sputum specimens and reduce the viability of <i>Mycobacterium tuberculosis</i> complex prior to further processing on the BD MAX™ System.
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
443806	BD MAX™ STR	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 11:32:10 PM GMT DC6A638A32E64A8A91F9D8DE330F0415 </div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial Release
02	Changed to New template CBI-058 FRM24-Revision 04. Modified Product, Basic UDI-DI and Intended purpose section to table format. Removed “Not Available” from Common Specifications table. Updated “On behalf of” with Legal Manufacturer’s Name. Formatting changes.