

## EU DECLARATION OF CONFORMITY (DoC)

<b>Manufacturer:</b>	Becton Dickinson GmbH Tullastrasse 8 – 12 69126 Heidelberg, Germany		
<b>Manufacturer SRN:</b>	DE-MF-000018170		
<b>Authorised Representative:</b>	Not applicable		
<b>Authorised Representative SRN:</b>	Not applicable		
<b>Product:</b>	<b>Catalog Number</b> 257107	<b>Product Trade Name</b> BD Tryptic Soy Broth (TSB)	
<b>Basic UDI-DI:</b>	<b>Catalog Number</b> 257107	<b>Product Trade Name</b> BD Tryptic Soy Broth (TSB)	<b>Basic UDI-DI</b> 038290FWPBDZAZDN
<b>Risk Class and Rule :</b>	Class A, Rule 5(a)		
<b>Intended Purpose:</b>	<b>Catalog Number</b> 257107	<b>Product Trade Name</b> BD Tryptic Soy Broth (TSB)	<b>Intended Purpose</b> BD Tryptic Soy Broth (Soybean-Casein Digest Medium) is a general purpose liquid enrichment medium used in qualitative procedures for the sterility test and for the enrichment and cultivation of aerobic microorganisms that are not excessively fastidious. In clinical microbiology, it may be used for the suspension, enrichment, and cultivation of strains isolated on other media.
<b>Notified Body:</b>	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"> <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:

Common specifications have not been issued for this product.

### Devices Covered by this DoC:

SKU#	Device Name	Device Class
257107	BD Tryptic Soy Broth (TSB)	Class A

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	Becton Dickinson GmbH
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	<div>DocuSigned by: <i>Anne Zavertnik</i></div> <div> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022   11:35:38 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

**DECLARATION OF CONFORMITY Revision History:**

<b>Version:</b>	<b>Detailed Change Description:</b>
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