

## EU DECLARATION OF CONFORMITY (DoC)


<b>Manufacturer:</b>	Becton, Dickinson and Company BD Biosciences 155 North McCarthy Boulevard, Milpitas, CA 95035 USA
<b>Manufacturer SRN:</b>	US-MF-000017797
<b>Authorised Representative:</b>	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland
<b>Authorised Representative SRN:</b>	IE-AR-000007610
<b>Product:</b>	BD <sup>®</sup> CS&T Beads (50 Test) <span style="border: 1px solid black; padding: 0 2px;">REF</span> 656504 BD <sup>®</sup> CS&T Beads (150 Test) <span style="border: 1px solid black; padding: 0 2px;">REF</span> 656505
<b>Basic UDI-DI:</b>	038290JJYVQAOSKG
<b>Risk Class and Rule :</b>	Class A, Annex VIII, Rule 5(a) & Rule 5(b)
<b>Intended Purpose:</b>	BD <sup>®</sup> CS&T Beads are used on a BD FACSLyric <sup>™</sup> flow cytometer to provide a standardized method to perform quality control of the instrument's optics, electronics, and fluidics. BD <sup>®</sup> CS&T Beads are also used for adjusting fluorescence compensation and for adjusting detector voltages.
<b>Notified Body:</b>	N/A
<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 In vitro Diagnostic Medical Devices.</li> </ul>	

### Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input checked="" type="checkbox"/> ANNEX I & II+III	N/A

**Common Specifications (CS):**

Common Specifications have not been issued for these products.

Authorised Signatory:	
Name & Title:	Mirna Dipano, Vice President, Regulatory Affairs
On behalf of:	Becton, Dickinson and Company BD Biosciences 155 North McCarthy Boulevard, Milpitas, CA 95035 USA
Place of Issue:	Milpitas, California USA
Date of Issue:	Please refer to Signature section.
Signature:	<div>DocuSigned by: <i>Mirna Dipano</i>  Signer Name: Mirna Dipano Signing Reason: I approve this document Signing Time: 30-May-2023   2:18:12 PM EDT 6166B70768DA44C1A0CA7A9871E2F40A</div>

**DECLARATION OF CONFORMITY Revision History:**

<b>Version:</b>	<b>Detailed Change Description:</b>
A	This DoC was created from a split of the initial BD FACSLytic™ system DoC and updated to use the corporate DoC template.
B	Update to Corporate Template CBI-058 FRM24 Revision 04. Updated Risk Class & Rule section by replacing “Class C, Rule 5” with “Class C, Annex VIII, Rule 5(a) & Rule 5(b)” to support global registration
C	Updated Authorized Signatory Table with the current Regulatory Affairs PRRC.
D	Updated the legal manufacturer address to 155 North McCarthy Boulevard, Milpitas, CA 95035 USA.