




## 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> FC Beads 7-Color Kit  656867 BD <sup>®</sup> FC Beads 5-Color Kit  661564 BD <sup>®</sup> FC Beads 2-Color Kit  662996
<b>Basic UDI-DI:</b>	038290ORYGOZMCPT
<b>Risk Class and Rule :</b>	Class A, Annex VIII, Rule 5(a) & Rule 5(b)
<b>Intended Purpose:</b>	The BD <sup>®</sup> FC Beads Kits are used to establish fluorescence compensation for a BD FACSLyric™ flow cytometer.
<b>Notified Body:</b>	N/A
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): <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><div>DocuSigned by: <i>Mirna Dipano</i></div><div> Signer Name: Mirna Dipano Signing Reason: I approve this document Signing Time: 30-May-2023   2:18:53 PM EDT 6166B70768DA44C1A0CA7A9871E2F40A</div></div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
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 A, Rule 5” with “Class A, Annex VIII, Rule 5(a) & Rule 5(b)” to support global registration
C	Updated Authorized Signatory Table with the current Regulatory Affairs PRRC. Updated the legal manufacturer address to 155 North McCarthy Boulevard, Milpitas, CA 95035 USA.