



EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company BD Biosciences 155 North McCarthy Boulevard Milpitas, California 95035 USA																
Manufacturer SRN:	US-MF-000017797																
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland																
Authorised Representative SRN:	IE-AR-000007610																
Product:	<table><tr><td>BD FACST[™] 7-Color Setup Beads</td><td>REF</td><td>666289</td></tr><tr><td>BD FACSDiva[™] CS&T IVD Beads (50 tests)</td><td>REF</td><td>656046</td></tr><tr><td>BD FACSDiva[™] CS&T IVD Beads (150 tests)</td><td>REF</td><td>656047</td></tr><tr><td>BD OneFlow[™] Setup Beads</td><td>REF</td><td>658620</td></tr><tr><td>BD® FC Beads 8-Color Kit for BD OneFlow[™] Assays</td><td>REF</td><td>658621</td></tr></table>		BD FACST [™] 7-Color Setup Beads	REF	666289	BD FACSDiva [™] CS&T IVD Beads (50 tests)	REF	656046	BD FACSDiva [™] CS&T IVD Beads (150 tests)	REF	656047	BD OneFlow [™] Setup Beads	REF	658620	BD® FC Beads 8-Color Kit for BD OneFlow [™] Assays	REF	658621
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Basic UDI-DI:	Product Trade Name	Basic UDI-DI															
	BD FACST [™] 7-Color Setup Beads	038290BSPWSCOYHB															
	BD FACSDiva [™] CS&T IVD Beads	038290CBFJJSUFY6															
	BD OneFlow [™] Setup Beads	038290CTEQEENN8D															
	BD® FC Beads 8-Color Kit for BD OneFlow [™] Assays	038290CTYWMHJDKS															
Risk Class and Rule:	Class A, Annex VIII Rule 5(a)																
Intended Purpose:	BD FACSDiva[™] CS&T IVD Beads BD FACSDiva [™] CS&T IVD Beads are intended for in vitro diagnostic use on BD FACSCanto [™] II flow cytometers running BD FACSDiva [™] software. BD FACSDiva [™] CS&T IVD Beads are used to set up the cytometer, to perform daily performance quality control (QC), and to determine lyse/wash (LW) application settings.																
	BD FACST[™] 7-Color Setup Beads BD FACST [™] 7-Color Setup Beads are for in vitro diagnostic use on a BD FACSCanto [™] or BD FACSCanto [™] II system. The beads are run with BD FACSCanto [™] Clinical Software. This system provides application-specific setup, including automated compensation and cytometer quality control (QC),																


	with minimal user intervention. It is also possible to import setup results generated by BD FACSCanto™ Clinical Software into BD FACSDiva™ software for further use with user-defined applications. Refer to your BD FACSCanto™ or BD FACSCanto™ II instructions for use (IFU).
	BD OneFlow™ Setup Beads BD OneFlow™ Setup Beads are intended to set voltages appropriate for the BD multicolor tube assay when used with a suitably equipped BD flow cytometer and software designated for in vitro diagnostic use.
	BD® FC Beads 8-Color kit for BD OneFlow™ Assays (BD® FC Beads) BD® FC Beads 8-Color Kit for BD OneFlow™ Assays (BD® FC Beads) are intended to allow software to determine spillover values (SOVs) for fluorescence compensation. BD® FC Beads are designed for use with a suitably equipped BD flow cytometer and software designated for in vitro diagnostic use.
Notified Body:	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"> Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices. 	

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 this product.

Authorised Signatory:	
Name & Title:	Mirna Dipano, Vice President, Regulatory Affairs
On behalf of:	Becton, Dickinson and Company BD Biosciences 155 North McCarthy Boulevard Milpitas, California 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: 05-Jul-2023 11:41:46 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A</div></div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
A	Original creation of document.
B	Update to conform with current Corporate Template CBI-058 FRM24 Revision 04. Updated Risk Class & Rule section by replacing “Class C, Rule 5” with “Class A, Annex VIII, Rule 5(a)” to support global registration
C	Updated grammar and formatting. Updated the legal manufacturer address and PRRC.