

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:	BD® Stem Cell Control REF 340991
Basic UDI-DI:	038290BKWKCP192
Risk Class and Rule:	Class B, Rule 6
Intended Purpose:	BD® Stem Cell Control is intended as a two-level process control with quantitative assigned values for use in immunophenotyping by a BD flow cytometer. It is a control for antibody staining, red blood cell (RBC) lysis, instrument setup and performance, and data analysis when used with the BD® Stem Cell Enumeration Kit.
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body Number: 2797
<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 In vitro Diagnostic Medical Devices. 	

Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: EC Certificate Expiration Date: Date:
<input checked="" type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: 728780 R000 EC Certificate Expiration Date: 2025-December-16
<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 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, CA 95035 USA
Place of Issue:	Milpitas , California USA
Date of Issue:	Please refer to Signature section.
Signature:	<div><div>DocuSigned by:</div><div>Mirna Dipano</div><div><div></div><div>Signer Name: Mirna Dipano Signing Reason: I approve this document Signing Time: 30-May-2023 2:00:59 PM EDT 6166B70768DA44C1A0CA7A9871E2F40A</div></div></div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
A	Initial creation of document
B	Update to Regulatory Affairs PRRC name.
C	Updated the legal manufacturer address to 155 North McCarthy Boulevard, Milpitas, CA 95035 USA.