

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 Multi-Check™ Control 1 x 2.5 mL	REF	340911
	BD Multi-Check™ Control 2 x 2.5 mL	REF	340912
	BD Multi-Check™ Control 5 x 2.5 mL	REF	340913
Basic UDI-DI:	038290DYCWQUCGGJ		
Risk Class and Rule:	Class C, Annex VIII, Rule 1.6		
Intended Purpose	BD Multi-Check™ Control is intended as a process control with quantitative assigned values for use in immunophenotyping by flow cytometry. It is a control for antibody staining, red blood cell (RBC) lysis, instrument setup and performance, and data analysis on BD FACSLytic™ flow cytometers when used with BD Multitest™ or BD Tritest™ reagents, with or without BD Trucount™ Tubes.		
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body Number: 2797		
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): 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 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, California 95035 USA
Place of Issue:	Milpitas, California USA
Date of Issue:	Please refer to Signature section.
Signature:	<div> DocuSigned by:   Signer Name: Mirna Dipano Signing Reason: I approve this document Signing Time: 30-Jun-2023 8:45:58 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A </div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Original creation of document.
B	Update to Corporate Template CBI-058 FRM24 Revision 04. Updated Risk Class & Rule section by replacing “Class C, Rule 1.6” with “Class C, Annex VIII, Rule 1.6” to support global registration
C	Updated formatting and grammar. Updated the legal manufacturer address and PRRC.