

## EU DECLARATION OF CONFORMITY (DoC)


<b>Manufacturer:</b>	Becton, Dickinson and Company BD Biosciences 155 North McCarthy Boulevard Milpitas, California 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® FMC7 FITC <span style="border: 1px solid black; padding: 0 2px;">REF</span> 332786
<b>Basic UDI-DI:</b>	038290RZYLELBQT2
<b>Risk Class and Rule:</b>	Class C, Annex VIII, Rule 3(g) & Rule 3(h)
<b>Intended Purpose:</b>	FMC7 is intended for in vitro diagnostic use in the identification of cells expressing the FMC7 antigen in peripheral blood, using a BD FACSLytic™ flow cytometer. <u>Clinical Applications</u> Expression of the FMC7 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia. FMC7 is a qualitative reagent intended for laboratory professional use only.
<b>Notified Body:</b>	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):	
<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 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:	
<b>Name &amp; Title:</b>	Mirna Dipano, Vice President, Regulatory Affairs
<b>On behalf of:</b>	Becton, Dickinson and Company BD Biosciences 155 North McCarthy Boulevard Milpitas, California 95035 USA
<b>Place of Issue:</b>	Milpitas, California USA
<b>Date of Issue:</b>	Please refer to Signature section.
<b>Signature:</b>	<div>  <p>DocuSigned by: Mirna Dipano</p> <p>Signer Name: Mirna Dipano Signing Reason: I approve this document Signing Time: 05-Jul-2023   11:41:18 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A</p> </div>

## DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Original creation of document.
B	Updated to use corporate DoC template. Added SRN for legal manufacturer.
C	Updated to current Corporate Template CBI-058 FRM24 Revision 04. Removed the “Devices covered by this DoC” table and incorporated the product details in the product section in the first table. Updated Risk Class & Rule section by replacing “Class C, Annex VIII Rule 3” with “Class C, Annex VIII, Rule 3(g) & Rule 3(h)” to support global registration, and removed the Template Revision History section.
D	Updated grammar and formatting. Updated the legal manufacturer address and PRRC.