

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 and Company Donore Road, Drogheda Co. Louth, A92 YW26 Ireland
Authorised Representative SRN:	IE-AR-000007610
Product:	BD® Anti-TCR- γ/δ (11F2) PE REF 333141
Basic UDI-DI:	038290WXVRL0TMZ8
Risk Class and Rule :	Class C, Annex VIII, Rule 3(g) & Rule 3(h)
Intended Purpose:	<p>Anti-TCR-γ/δ (11F2) is intended for in vitro diagnostic use in the identification of cells expressing the TCR-γ/δ antigen in peripheral blood, using a BD FACSLytic™ flow cytometer.</p> <p><u>Clinical Applications</u></p> <p>Expression of the TCR-γ/δ antigen in the characterization of subjects having, or suspected of having, hematological neoplasia.</p> <p>Anti-TCR-γ/δ (11F2) is a qualitative reagent intended for laboratory professional use only.</p>
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:
<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: 07-Jul-2023 11:26:49 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A </div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Initial creation of document
B	Update to accommodate with Corporate Template CBI-058 FRM24. Added SRN for legal manufacturer.
C	Updated to Corporate Template CBI-058 FRM24 Revision 04. 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.
D	Updated legal manufacturing address to Milpitas site to support project curie. Updated Authorised Signatory to include new PRRC. Updated product description names to include trademarks