

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:	<div> <div>BD® CD3 (SK7) FITC (50 tests)</div> <div>REF 345763</div> </div> <div> <div>BD® CD3 (SK7) FITC (250 tests)</div> <div>REF 345764</div> </div> <div> <div>BD® CD3 (SK7) PE</div> <div>REF 345765</div> </div> <div> <div>BD® CD3 (SK7) PerCP</div> <div>REF 345766</div> </div> <div> <div>BD® CD3 (SK7) PerCP-Cy5.5</div> <div>REF 332771</div> </div> <div> <div>BD® CD3 (SK7) PE-Cy7</div> <div>REF 341111</div> </div> <div> <div>BD® CD3 (SK7) APC</div> <div>REF 345767</div> </div> <div> <div>BD® CD3 (SK7) APC-Cy7</div> <div>REF 341110</div> </div> <div> <div>BD® CD3 (SK7) APC-H7</div> <div>REF 641415</div> </div> <div> <div>BD® CD3 (SK7) V500-C</div> <div>REF 652896</div> </div>
Basic UDI-DI:	038290LAQOEQEF8C
Risk Class and Rule :	Class C, Annex VIII, Rule 3(g) & Rule 3(h)
Intended Purpose:	<p>CD3 (SK7) is intended for in vitro diagnostic use in the identification of cells expressing the CD3 antigen in peripheral blood, using a BD FACSLyric™ flow cytometer.</p> <p><u>Clinical Applications</u></p> <p>Expression of the CD3 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia.</p> <p>CD3 (SK7) 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



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><div>DocuSigned by:</div><div>Mirna Dipano</div><div> Signer Name: Mirna Dipano Signing Reason: I approve this document Signing Time: 07-Jul-2023 11:27:11 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A</div></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	Aligned versioning of the document with SAP versioning as version C of the document was released as version D in SAP
E	Updated formatting and grammar throughout the document. Updated SKU 652896 Product Description. Updated Manufacturer and Authorised Signatory to include Milpitas address. Updated Name & Title section to current PRRC. Updated product description names to include trademarks.