

EU DECLARATION OF CONFORMITY (DoC)



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| 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- α/β (WT31) FITC REF 333140 |
| Basic UDI-DI: | 038290QMGMHGWDW |
| Risk Class and Rule: | Class C, Annex VIII, Rule 3(g) & Rule 3(h) |
| Intended Purpose: | <p>Anti-TCR-α/β (WT31) is intended for in vitro diagnostic use in the identification of cells expressing the TCR-α/β antigen in peripheral blood, using a BD FACSLyric™ flow cytometer.</p> <p><u>Clinical Applications</u></p> <p>Expression of the TCR-α/β antigen in the characterization of subjects having, or suspected of having, hematological neoplasia.</p> <p>Anti-TCR-α/β (WT31) 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:

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| <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: 05-Jul-2023 4:09:03 PM 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 grammar and formatting. 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. |