

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 Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland | | |
| Authorised Representative SRN: | IE-AR-000007610 | | |
| Product: | BD® CD45 (2D1) FITC | REF | 345808 |
| | BD® CD45 (2D1) PerCP | REF | 345809 |
| | BD® CD45 (2D1) PerCP-Cy™5.5 | REF | 332784 |
| | BD® CD45 (2D1) APC | REF | 340910 |
| | BD® CD45 (2D1) APC-Cy™7 | REF | 348815 |
| | BD® CD45 (2D1) APC-H7 | REF | 641417 |
| | BD® CD45 (2D1) V500-C | REF | 655873 |
| Basic UDI-DI: | 038290ZXJMVGTRVN | | |
| Risk Class and Rule: | Class C, Annex VIII, Rule 3(g) & Rule 3(h) | | |
| Intended Purpose | CD45 (2D1) is intended for in vitro diagnostic use in the identification of cells expressing the CD45 antigen in peripheral blood, using a BD FACSLytic™ flow cytometer. <u>Clinical Applications</u> Expression of the CD45 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia. CD45 (2D1) is a qualitative reagent intended for laboratory professional use only. | | |
| 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): <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: 03-Jul-2023 10:45:38 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A </div> |

DECLARATION OF CONFORMITY Revision History:

| Version: | Detailed Change Description: |
|----------|---|
| A | Original creation of document. |
| B | Updated SRN of EU Authorized Representative |
| C | Updated to align with Corporate Template CBI-058 |
| D | Update to current 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. |
| E | Updated grammar and formatting. Updated the legal manufacturer address and PRRC. |