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:	BD® CD5 (L17F12) FITC REF 345781 BD® CD5 (L17F12) PerCP-Cy5.5 REF 341109 BD® CD5 (L17F12) APC REF 345783 BD® CD5 (L17F12) PE REF 345782 BD® CD5 (L17F12) PE-Cy7 REF 348810
Basic UDI-DI:	038290WJIKBDPZEM
Risk Class and Rule :	Class C, Annex VIII, Rule 3(g) & Rule 3(h)
Intended Purpose:	CD5 (L17F12) is intended for in vitro diagnostic use in the identification of cells expressing the CD5 antigen in peripheral blood, using a BD FACSLyric™ flow cytometer Clinical Applications Expression of the CD5 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia. CD5 (L17F12) 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):

- Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices.

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Conformity Assessment Route:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
☒ ANNEX IX Full Quality System	EC CERTIFICATE No.: 728780 R000 EC Certificate Expiration Date: 2025-December-16
☐ ANNEX X Type Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
☐ 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:	DocuSigned by: Mirna Dipano Signer Name: Mirna Dipano Signing Reason: I approve this document Signing Time: 05-Jul-2023 | 4:10:20 PM PDT 6166B70768DA44C1A0CA7A9871E2F40A

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Initial creation of document
B	Updated SRN of EU Authorized Representative
C	Update to accommodate with Corporate Template CBI-058 FRM24. Added SRN for legal manufacturer.
D	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.
E	Updated manufacturer and Authorised Signatory to include Milpitas address. Updated Name & Title section to include current PRRC. Updated product description names to include trademarks.

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