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® CD19 (SJ25C1)** BD® CD19 (SJ25C1) FITC REF 345788 BD® CD19 (SJ25C1) PE REF 345789 BD® CD19 (SJ25C1) PerCP REF 345790 BD® CD19 (SJ25C1) PerCP-Cy5.5 REF 332780 BD® CD19 (SJ25C1) PE-Cy7 REF 341113 BD® CD19 (SJ25C1) APC REF 345791 BD® CD19 (SJ25C1) APC-Cy7 REF 348814 **BD® CD19 (4G7)** BD® CD19 (4G7) FITC REF 345776 BD® CD19 (4G7) PE REF 345777 BD® CD19 (4G7) PerCP REF 345778
Basic UDI-DI:	038290OZKDOEIGHX
Risk Class and Rule:	Class C, Annex VIII, Rule 3(g) & Rule 3(h)
Intended Purpose:	**BD® CD19 (SJ25C1)** CD19 (SJ25C1) is intended for in vitro diagnostic use in the identification of cells expressing the CD19 antigen in peripheral blood, using a BD FACSLyric™ flow cytometer. Clinical Applications Expression of the CD19 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia. CD19 (SJ25C1) is a qualitative reagent intended for laboratory professional use only.

	BD® CD19 (4G7) CD19 (4G7) is intended for in vitro diagnostic use in the identification of cells expressing the CD19 antigen in peripheral blood, using a BD FACSLyric™ flow cytometer. Clinical Applications Expression of the CD19 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia. CD19 (4G7) 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.	

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 | 11:39:46 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Original creation of document.
B	Updated to use corporate DoC template. Added SRN for legal manufacturer. Updated the intended use to include BD CD19 (4G7) intended use.
C	Updated to current Corporate Template CBI-058 FRM24 Revision 04. Removed the "Devices covered by this DoC" table and incorporated the product details in the product section in the first table. 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, and removed the Template Revision History section.
D	Updated grammar and formatting. Updated the legal manufacturer address and PRRC.