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® CD34 (8G12) FITC REF 345801 BD® CD34 (8G12) PE REF 345802 BD® CD34 (8G12) PerCP REF 345803 BD® CD34 (8G12) PerCPCy5.5 REF 347222 BD® CD34 (8G12) PE-Cy7 REF 348811 BD® CD34 (8G12) APC REF 345804
Basic UDI-DI:	038290MFFTSINZCR
Risk Class and Rule:	Class C, Annex VIII, Rule 3(g) & Rule 3(h)
Intended Purpose:	CD34 (8G12) is intended for in vitro diagnostic use in the identification of cells expressing the CD34 antigen in peripheral blood, using a BD FACSLyric™ flow cytometer. Clinical Applications Expression of the CD34 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia. CD34 (8G12) 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: 30-Jun-2023 | 8:47:14 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Original creation of document.
B	Update 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, and removed the Template Revision History section. Included the detailed address of the Notified Body. Updated the Date of Issue section in the Authorised Signatory table from date generated from DocuSign to "Please refer to Signature section."
C	Updated grammar and formatting. Updated the legal manufacturer address and PRRC.