

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® CD38 (HB7) FITC	<div>REF</div>	340909
	BD® CD38 (HB7) PE	<div>REF</div>	345806
	BD® CD38 (HB7) PE-Cy7	<div>REF</div>	335825
	BD® CD38 (HB7) APC	<div>REF</div>	345807
	BD® CD38 (HB7) BV605	<div>REF</div>	664451
Basic UDI-DI:	038290DXSEMCQREM		
Risk Class and Rule:	Class C, Annex VIII, Rule 3(g) & Rule 3(h)		
Intended Purpose:	CD38 (HB-7) is intended for in vitro diagnostic use in the identification of cells expressing the CD38 antigen in peripheral blood, using a BD FACSLytic™ flow cytometer. <u>Clinical Applications</u> Expression of the CD38 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia. CD38 (HB-7) 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:

<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 10:46:42 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A </div>

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.