

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® CD10 (HI10a) FITC	REF	332775
	BD® CD10 (HI10a) PE	REF	332776
	BD® CD10 (HI10a) PE-Cy7	REF	341112
	BD® CD10 (HI10a) APC	REF	332777
	BD® CD10 (HI10a) APC-R700	REF	664453
Basic UDI-DI:	038290YNAJNVPIJQ		
Risk Class and Rule:	Class C, Annex VIII, Rule 3(g) & Rule 3(h)		
Intended Purpose:	CD10 (HI10a) is intended for in vitro diagnostic use in the identification of cells expressing the CD10 antigen in peripheral blood, using a BD FACSLytic™ flow cytometer. <u>Clinical Applications</u> Expression of CD10 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia. CD10 (HI10a) 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>  <p>DocuSigned by: Mirna Dipano</p> <p>Signer Name: Mirna Dipano Signing Reason: I approve this document Signing Time: 05-Jul-2023 11:38:13 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A</p> </div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Original creation of document.
B	Updated CD10(HI10a) Per-Cy7 Product Description. Updated the document number in the header.
C	Update to Corporate Template. Inclusion of CD10 (HI10a) APC-R700 and Manufacturer SRN.
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, and removed the Template Revision History section.
E	Updated grammar and formatting. Updated the legal manufacturer address and PRRC.