



## EU DECLARATION OF CONFORMITY (DoC)



<b>Manufacturer:</b>	Becton, Dickinson and Company BD Biosciences 155 North McCarthy Boulevard Milpitas, California 95035 USA		
<b>Manufacturer SRN:</b>	US-MF-000017797		
<b>Authorised Representative:</b>	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland		
<b>Authorised Representative SRN:</b>	IE-AR-000007610		
<b>Product:</b>	BD® CD103 (Ber-ACT8) FITC		333155
	BD® CD103 (Ber-ACT8) PE		333156
<b>Basic UDI-DI:</b>	038290DJQTYSBQF7		
<b>Risk Class and Rule:</b>	Class C, Annex VIII, Rule 3(g) & Rule 3(h)		
<b>Intended Purpose</b>	<p>CD103 (Ber-ACT8) is intended for in vitro diagnostic use in the identification of cells expressing the CD103 antigen in peripheral blood, using a BD FACSLytic™ flow cytometer.</p> <p><u>Clinical Applications</u></p> <p>Expression of the CD103 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia.</p> <p>CD103 (Ber-ACT8) is a qualitative reagent intended for laboratory professional use only.</p>		
<b>Notified Body:</b>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body Number: 2797		
<p>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):</p> <ul style="list-style-type: none"><li>Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices.</li></ul>			

## 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:	
<b>Name &amp; Title:</b>	Mirna Dipano, Vice President, Regulatory Affairs
<b>On behalf of:</b>	Becton, Dickinson and Company BD Biosciences 155 North McCarthy Boulevard Milpitas, California 95035 USA
<b>Place of Issue:</b>	Milpitas, California USA
<b>Date of Issue:</b>	Please refer to Signature section.
<b>Signature:</b>	<div> DocuSigned by:     Signer Name: Mirna Dipano  Signing Reason: I approve this document  Signing Time: 30-Jun-2023   8:47:48 AM PDT  6166B70768DA44C1A0CA7A9871E2F40A </div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
A	Original creation of document.
B	Update to current Corporate Template CBI-058 FRM24 Revision 04 and updated the Risk Class and Rule Section. Removed the Template Revision History section.
C	Updated grammar and formatting. Updated the legal manufacturer address and PRRC.