

## 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>	<table border="0"> <tr> <td>BD® CD20 (L27) FITC</td><td><b>REF</b></td><td>345792</td></tr> <tr> <td>BD® CD20 (L27) PE</td><td><b>REF</b></td><td>345793</td></tr> <tr> <td>BD® CD20 (L27) PerCP</td><td><b>REF</b></td><td>345794</td></tr> <tr> <td>BD® CD20 (L27) PerCP-Cy5.5</td><td><b>REF</b></td><td>332781</td></tr> <tr> <td>BD® CD20 (L27) PE-Cy7</td><td><b>REF</b></td><td>335828</td></tr> <tr> <td>BD® CD20 (L27) APC</td><td><b>REF</b></td><td>340908</td></tr> <tr> <td>BD® CD20 (L27) APC-Cy7</td><td><b>REF</b></td><td>335829</td></tr> <tr> <td>BD® CD20 (L27) APC-H7</td><td><b>REF</b></td><td>641414</td></tr> <tr> <td>BD® CD20 (L27) V450</td><td><b>REF</b></td><td>655872</td></tr> </table>	BD® CD20 (L27) FITC	<b>REF</b>	345792	BD® CD20 (L27) PE	<b>REF</b>	345793	BD® CD20 (L27) PerCP	<b>REF</b>	345794	BD® CD20 (L27) PerCP-Cy5.5	<b>REF</b>	332781	BD® CD20 (L27) PE-Cy7	<b>REF</b>	335828	BD® CD20 (L27) APC	<b>REF</b>	340908	BD® CD20 (L27) APC-Cy7	<b>REF</b>	335829	BD® CD20 (L27) APC-H7	<b>REF</b>	641414	BD® CD20 (L27) V450	<b>REF</b>	655872
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<b>Basic UDI-DI:</b>	038290EJVVPOAAET																											
<b>Risk Class and Rule:</b>	Class C, Annex VIII, Rule 3(g) & Rule 3(h)																											
<b>Intended Purpose:</b>	<p>CD20 (L27) is intended for in vitro diagnostic use in the identification of cells expressing the CD20 antigen in peripheral blood, using a BD FACSLyric™ flow cytometer.</p> <p><u>Clinical Applications</u></p> <p>Expression of the CD20 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia.</p> <p>CD20 (L27) 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: 05-Jul-2023   11:39:59 AM PDT  6166B70768DA44C1A0CA7A9871E2F40A </div>

## DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Original creation of document.
B	Updated the intended use for CD20 (L27)
C	Updated to use corporate DoC template. Added SRN for legal manufacturer.
D	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.
E	Updated grammar and formatting. Updated the legal manufacturer address and PRRC.