

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® CD138 (MI15) FITC	<div>REF</div>	347214
	BD® CD138 (MI15) PE	<div>REF</div>	347215
	BD® CD138 (MI15) PerCP-Cy5.5	<div>REF</div>	341107
	BD® CD138 (MI15) APC	<div>REF</div>	347216
	BD Horizon™ CD138 (MI15) BV421	<div>REF</div>	665418
Basic UDI-DI:	038290RTRWIPESU		
Risk Class and Rule:	Class C, Annex VIII, Rule 3(g) & Rule 3(h)		
Intended Purpose:	CD138 (MI15) is intended for in vitro diagnostic use in the identification of cells expressing the CD138 antigen in peripheral blood, using a BD FACSLyric™ flow cytometer. <u>Clinical Applications</u> Expression of the CD138 antigen in the characterization of subjects having, or suspected of having, hematological neoplasia. CD138 (MI15) 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: 10-Jul-2023 8:56:59 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. 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.
C	Addition of BD Horizon™ CD138 (MI15) BV421. Minor grammatical clarification.
D	Updated grammar and formatting. Updated the legal manufacturer address and PRRC.