

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 FACST [™] Lysing Solution REF 349202
Basic UDI-DI:	038290EWGRQTXZJY
Risk Class and Rule :	Class A, Annex VIII, Rule 5(a)
Intended Purpose:	BD FACST [™] Lysing Solution is intended for lysing red blood cells for flow cytometric applications. It can be used in both lyse/wash and lyse/no-wash procedures.
Notified Body:	N/A
<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"> 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 type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
<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 checked="" 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><div>DocuSigned by: <i>Mirna Dipano</i></div><div> Signer Name: Mirna Dipano Signing Reason: I approve this document Signing Time: 27-Jun-2023 5:53:25 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A</div></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 A, Rule 5” with “Class A, Annex VIII, Rule 5(a)” to support global registration. Included the manufacturer SRN and Classification Rule. Updated the Date of Issue section in the Authorised Signatory table from date generated from DocuSign to “Please refer to Signature section.”
C	Updated the legal manufacturer address and PRRC.