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 Multitest™ IMK Kit	REF 340503
	BD Multitest™ IMK Kit with BD Trucount™ Tubes	REF 340504
Basic UDI-DI:	BD Multitest™ IMK Kit	038290QPFUXCDZKZ
	BD Multitest™ IMK Kit with BD Trucount™ Tubes	038290HZBMIJDBBW
Risk Class and Rule :	Class C, Annex VIII, Rule 3(e) & Rule 3(k)	
Intended Purpose:	The BD Multitest™ IMK Kit with optional BD Trucount™ Tubes is a 4-color direct immunofluorescence reagent kit for use in identifying and determining the percentages and absolute counts of T, B, and natural killer (NK) cells, as well as the CD4 and CD8 subpopulations of T cells, in peripheral blood on a BD flow cytometer equipped with the following: ▪ At least a 488-nm blue laser and a 640-nm red laser ▪ The ability to detect forward scatter (FSC) and side scatter (SSC) ▪ At least 4-color fluorescence ▪ Software to acquire and analyze the data <u>Clinical Applications</u> Determining percentages or absolute counts of $CD3^+CD4^+$ T lymphocytes is used in monitoring human immunodeficiency virus (HIV)-infected individuals. Individuals with HIV typically exhibit a steady decrease of $CD3^+CD4^+$ T-lymphocyte absolute counts as the infection progresses. Determining percentages or absolute counts of $CD3^+$, $CD3^+CD4^+$ or $CD3^+CD8^+$ T lymphocytes or $CD19^+$ B lymphocytes is used to characterize or monitor some forms of immune deficiency and autoimmune diseases. Determining percentages or absolute counts of $CD3^-$ and $CD16^+$ and/or $CD56^+$ NK lymphocytes is used in immunological assessment of hematologically-normal subjects or patients having, or suspected of having, immune deficiency or other immune-mediated diseases.	
Notified Body:	BSI Group The Netherlands B.V.	

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Status: Released EFFECTIVE
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Version: D
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	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): • Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices.	

Conformity Assessment Route:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
☒ ANNEX IX Full Quality System	EC CERTIFICATE No.: 728780 R000 EC Certificate Expiration Date: 2025-December-16
☐ ANNEX X Type Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
☐ 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:	DocuSigned by: Mirna Dipano Signer Name: Mirna Dipano Signing Reason: I approve this document Signing Time: 17-Jul-2023 | 6:07:33 AM PDT 6166B70768DA44C1A0CA7A9871E2F40A

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
A	Original Creation of document
B	Update legal manufacturer and authorized representative SRN, add “place of issue” information, update template.
C	Updated to Corporate Template CBI-058 FRM24 Revision 04. Updated Intended Purpose with generic instrument claim and the Authorized Signatory Section. Updated Risk Class & Rule section by replacing “Class C, Rule 2.3 (e) and Rule 2.3 (k) under Rule 3” with “Class C, Annex VIII, Rule 3(e) & Rule 3(k) to support global registration”. Updated to Corporate Template CBI-058 FRM24 Revision 04.
D	Updated the legal manufacturer address and PRRC. Updated trademarks in device name.

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