



BD *Declaration of Conformity*

Manufacturer:	Becton, Dickinson and Company BD Biosciences 2350 Qume Drive San Jose, CA 95131, USA Tel: 877.232.8995 / Fax: 408.954.2347
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 / Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	332785 - CD117 (104D2) PE 333233 - CD117 (104D2) APC 333950 - CD117 (104D2) PerCP-Cy (TM) 5.5 339217 - CD117 (104D2) PE-Cy (TM) 7
<p>We hereby declare that the above mentioned product(s) manufactured after 2017/10/01 complies with the above listed Directive(s) and its relevant transposition into national laws of the member states into which we place the devices.</p>	
Signed In San Jose:	2017/10/01
Name and Authority:	Paul Arrendell, WW VP Quality Management
Signature:	

Technical File Number:

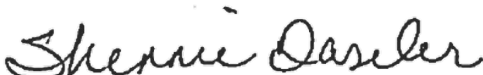


Declaration of Conformity

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Conformity Assessment Procedure:	IVD Directive 98/79/EC, Annex III
Product(s) Conforming to IVD Directive:	658621 - BD™ FC Beads 8-Color Kit for BD OneFlow™ Assays 658620 - BD OneFlow™ Setup Beads 658619 - BD OneFlow™ LST 659912 - BD OneFlow™ PCST 659913 - BD OneFlow™ PCD 659293 - BD OneFlow™ B-CLPD T1 660228 - BD OneFlow™ ALOT 659305 - BD OneFlow™ Assays System 664225 - BD OneFlow™ Assays Installer I 664226 - BD OneFlow™ Assays Installer II

This Declaration of Conformity is issued under the sole responsibility of Becton, Dickinson and Company, BD Biosciences.

We hereby declare that the above mentioned product(s) complies with the above referenced Directive(s) and its relevant transposition into national laws of the member states into which we place the devices.

Name and Authority in San Jose:	Sherrie Daseler, WW Vice President, Quality Management
QA Authority Signature 	Date 03 Sept 2020

Document Number: 10000331990, Ver. E



10000331990, Ver. E

CE-IVD – Declaration of Conformity - OneFlow

NOTE: Print all pages prior to this page if providing it as a hard copy.

Version History		
Version	Description of Changes	Date of Completion
A	Initial release	30AUG2017
B	See legacy	11JAN2018
C	Using updated Declaration of Conformity template SOP6009-06	10AUG2018
D	Added 664225 - BD OneFlow™ Assays Installer I and 664226 - BD OneFlow™ Assays Installer II; updated Quality VP to current.	01SEP2020
E	Corrected minor Typos (TM missing and Assay updated to Assays). No change to technical content.	See Watermark

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Becton, Dickinson and Company (BD)
7 Loveton Circle
Sparks
Maryland
21152
USA

Holds Certificate Number:

MD 595740

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, prepared media products, dehydrated culture media, collection and transport, antimicrobial susceptibility tests, sample preparation, cytology devices, cytopathology auto-imaging devices with computerized microscopy, telepathology devices, lab automation, ancillary devices and instrument software.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2013-03-14

Latest Revision Date: 2019-04-11

Effective Date: 2018-10-11

Expiry Date: 2021-10-10

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Certificate No: **MD 595740**

Location	Registered Activities
Becton, Dickinson and Company (BD) 7 Loveton Circle Sparks Maryland 21152 USA	The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, prepared media products, dehydrated culture media, collection and transport, antimicrobial susceptibility tests, sample preparation, cytology devices, cytopathology auto-imaging devices with computerized microscopy, telepathology devices, lab automation, ancillary devices and instrument software.
Becton Dickinson and Company (BD) BD Diagnostic Systems 52/54 Loveton Circle Sparks, Maryland 21152 USA	The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, prepared media products, dehydrated culture media, collection and transport, sample preparation.
Becton Dickinson and Company (BD) BD Diagnostic Systems 39 Loveton Circle Sparks, Maryland 21152 USA	The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, dehydrated culture media, collection and transport, sample preparation.
Becton Dickinson and Company (BD) BD Diagnostic Systems 250 Schilling Circle Cockeysville, Maryland 21030 USA	The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, prepared media products, collection and transport, antimicrobial susceptibility tests, sample preparation.

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