By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 728780 R000

Manufacturer: Becton, Dickinson and Company BD Biosciences

Address:
2350 Qume Drive
San Jose
California
95131
USA

Single Registration Number: US-MF-000017797

EU Authorised Representative: Becton Dickinson Ireland Limited

Address:
Donore Road
Drogheda
Co. Louth
A92 YW26
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2020-12-17** Date: **2022-08-17** Expiry Date: **2025-12-16**

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Device Schedule:

Class C near-patient test devices	Intended purpose
BD FACSPresto™ Cartridge	See EU Technical Documentation Assessment Certificate – IVDR 728782
BD FACSPresto™ Cartridge Kit	See EU Technical Documentation Assessment Certificate – IVDR 728782

Class C Devices	Intended purpose
W010308 – Monoclonal Antibodies / Flow Cytometry; **IVP3006 –** In vitro diagnostic devices which require knowledge regarding flow cytometry; **IVR0504 -** Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging	Haematology devices intended to be used for identification and enumeration of leukocyte populations for determination of the infectious load, infective disease status or immune status and devices used for infectious disease staging using flow cytometry, and associated controls.
W010308 – Monoclonal Antibodies / Flow Cytometry; **IVP3006 –** In vitro diagnostic devices which require knowledge regarding flow cytometry; **IVR0302 -** Other devices intended to be used for markers of cancer and non-malignant tumours	Single colour fluorescent antibodies for identification of leukocyte antigens in the characterization of haematologic neoplasia using flow cytometry.
W010308 – Monoclonal Antibodies / Flow Cytometry; **IVP3006 –** In vitro diagnostic devices which require knowledge regarding flow cytometry; **IVR0301 -** Devices intended to be used for screening, diagnosis, staging or monitoring of cancer	Panels of fluorochrome-conjugated antibodies for qualitative flow-cytometric immunophenotyping of hematologic cell population as an aid in the differential diagnosis of hematologic disorders.

Class B Devices	Intended purpose
IVR0608 – Devices intended to be used for screening, determination or monitoring of physiological markers	Devices intended to be used for the enumeration of CD45+/CD34+ hematopoietic stem cell populations and residual white blood cells using flow cytometry, and associated controls.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2020-12-17	3205711	First Issue
2021-06-05	3421868	Supplemented – Addition of devices to Generic Device Group "W010308 – Monoclonal Antibodies / Flow Cytometry; IVP3006 – In vitro diagnostic devices which require knowledge regarding flow cytometry; IVR0302 - Other devices intended to be used for markers of cancer and non-malignant tumours"
2021-08-16	3490899	Amended – Change of authorised representative to Becton Dickinson Ireland Limited. Supplemented – Addition of Generic Device Group "W010308 – Monoclonal Antibodies / Flow Cytometry; IVP3006 – In vitro diagnostic devices which require knowledge regarding flow cytometry; IVR0301 – Devices intended to be used for screening, diagnosis, staging or monitoring of cancer"
2021-11-10	3539454	Supplemented – Addition of devices to generic device group "W010308 – Monoclonal Antibodies / Flow Cytometry; IVP3006 – In vitro diagnostic devices which require knowledge regarding flow cytometry; IVR0504 - Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging, and update of intended use statement.
2022-03-29	3634114	Supplemented – addition of the BD FACSPresto™ Cartridge and BD FACSPresto™ Cartridge Kit devices. Amended – addition of SRN, US-MF-000017797

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Current	3704124	Supplemented – addition of Device Category IVR0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

IVDR 728780 R000

Date: **2022-08-17**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Becton Dickinson Caribe, Ltd. Vick's Drive, Lot 1 Corner Road 735 Cayey 00736 Puerto Rico	**Manufacture**

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