

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Becton, Dickinson and Company
BD Biosciences
2350 Qume Drive
San Jose
California
95131
USA

DUNS Number: 00-129-2192

Holds certificate No:

MDSAP 690529

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1-SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

The design, development, manufacture, service, and distribution of invitro diagnostic, clinical, and research devices, reagents, instruments (including flow cytometers), and software for cell sorting and enumeration of tissue and biological fluid samples such as blood and blood components.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-01-11

Effective Date: 2019-01-11

Expiry date: 2021-09-15

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BSI Group America Inc. is an MDSAP authorized auditing organization

Certificate No: **MDSAP 690529**

Location	Registered Activities
Becton, Dickinson and Company BD Biosciences 2350 Qume Drive San Jose California 95131 USA DUNS Number: 00-129-2192	The design, development, manufacture, service, and distribution of invitro diagnostic, clinical, and research devices, reagents, instruments (including flow cytometers), and software for cell sorting and enumeration of tissue and biological fluid samples such as blood and blood components.
Becton, Dickinson and Company BD Biosciences 48541 Warm Springs Blvd. Suite 509 Fremont California 94539 USA	Inventory Control.
Becton, Dickinson and Company BD Biosciences 2150 Commerce Drive San Jose California 95131 USA	Repair.



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