

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Terumo BCT, Inc.
10811 W. Collins Ave.
Lakewood
Colorado
80215
USA

Facility ID Number: F000445

Holds Certificate No:

MDSAP 692625

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; 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, distribution and servicing of automated blood collection systems, blood cell processor systems, apheresis system, medical device software, systems for storage, pathogen reduction and WBC Inactivation of Blood Components using Riboflavin and UV Light.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-04-22

Effective Date: 2022-04-22

Expiry Date: 2025-04-21



BSI Group America Inc. is an MDSAP authorized auditing organization

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