

Certificate of Registration

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

This is to certify that:

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

Holds Certificate Number:

MD 540428

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

Please see scope page.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2009-04-27

Latest Revision Date: 2019-04-17

Effective Date: 2019-04-28

Expiry Date: 2022-04-27

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Certificate No: **MD 540428**

Registered Scope:

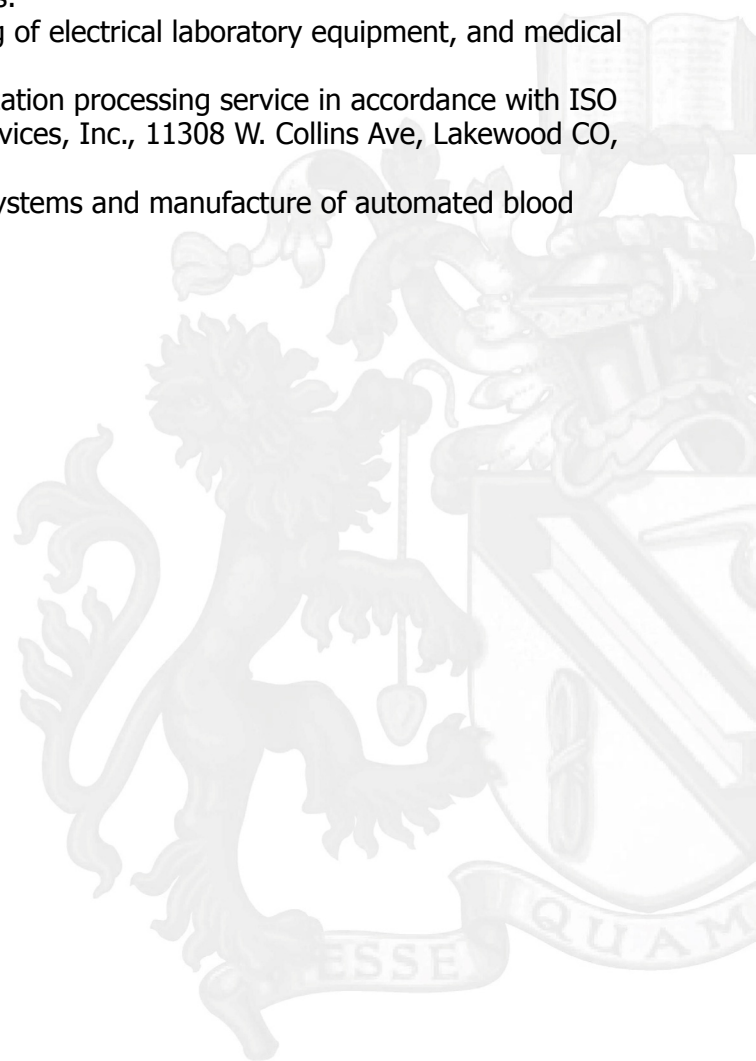
The design, development, manufacture, distribution and servicing of automated blood collection systems, manual blood collection systems, blood cell processor systems, apheresis systems, medical device software, systems for storage, pathogen reduction and WBC Inactivation of Blood and Blood Components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

Design, development, manufacture, distribution, installation and servicing of active Medical Devices, and accessories for IV administration, diabetes management and use in Transfusion Medicine. Distribution, installation and servicing of Terumo active Medical Devices.

The design and development, assembly, test and servicing of electrical laboratory equipment, and medical devices in the blood banking market.

The provision of subcontracted and Ethylene Oxide sterilization processing service in accordance with ISO 11135:2014 under the name Terumo BCT Sterilization Services, Inc., 11308 W. Collins Ave, Lakewood CO, USA, 80215-4424.

Manufacture and distribution of manual blood collection systems and manufacture of automated blood collection systems.



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Printed copies can be validated at www.bsigroup.com/ClientDirectory

Certificate No: **MD 540428**

Location	Registered Activities
Terumo BCT, Inc. 10811 W. Collins Avenue Lakewood Colorado 80215 USA	The design, development, manufacture, distribution and servicing of automated blood collection systems, blood cell processor systems, apheresis systems, medical device software, systems for storage, pathogen reduction and WBC Inactivation of Blood and Blood Components using Riboflavin and UV Light. The provision of subcontracted and Ethylene Oxide sterilization processing service in accordance with ISO 11135:2014 under the name Terumo BCT Sterilization Services, Inc., 11308 W. Collins Ave, Lakewood CO, USA, 80215-4424.
Terumo BCT Europe NV Ikarslaan 41 Zaventem B-1930 Belgium	The Distribution and Servicing of automated blood collection systems, blood cell processor systems and apheresis systems including associated sterile devices.
Terumo BCT Europe NV Romeinsestraat 8 Leuven B-3001 Belgium	Design, development, manufacture, distribution, installation and servicing of active Medical Devices, and accessories for IV administration, diabetes management and use in Transfusion Medicine. Distribution, installation and servicing of Terumo active Medical Devices.

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