



By Royal Charter

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-04-27

Latest Revision Date: 2022-04-25

Effective Date: 2022-04-28

Expiry Date: 2025-04-27

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 540428**

Registered Scope:

The design, development, manufacture, distribution and servicing of automated blood collection systems, manual blood collection systems, blood cell separator and 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.

Manufacture, distribution, installation and servicing of medical devices and nonsterile accessories for 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 contract and ethylene oxide sterilization services in accordance with applicable quality management system requirements within ISO 11135:2014.

The provision of technical, regulatory and clinical support services for locally marketed Terumo medical products.

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Location	Registered Activities
Terumo BCT, Inc. 10811 W. Collins Ave. 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 design and development, assembly, test and servicing of electrical laboratory equipment, and medical devices in the blood banking market.
Terumo BCT Europe N.V. Ikaroslaan 41 Zaventem 1930 Belgium	The servicing, sales, marketing, customer services and logistics of automated blood cell separator and processor systems, apheresis systems, including associated sterile devices. The provision of technical, regulatory and clinical support services for locally marketed Terumo medical products.
Terumo BCT Sterilization Services, Inc. 11308 West Collins Avenue Lakewood Colorado 80215 USA	The provision of contract and ethylene oxide sterilization services in accordance with applicable quality management system requirements within ISO 11135:2014.
Terumo BCT Europe N.V. Romeinsestraat 8 Leuven 3001 Belgium	Manufacture, distribution, installation and servicing of medical devices; and nonsterile accessories for use in transfusion medicine. Distribution, installation and servicing of Terumo active medical devices.

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