

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

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


Holds Certificate No:

FM 30402

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Please see scope page.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 1995-01-13

Latest Revision Date: 2019-04-23

Effective Date: 2019-04-26

Expiry Date: 2022-04-25

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...making excellence a habit.™

Certificate No: **FM 30402**

Registered Scope:

The design, development, manufacture, distribution and servicing of automated blood collection systems; blood cell processor systems and apheresis systems; systems for storage, pathogen reduction and WBC Inactivation of Blood and Blood Components using Riboflavin and UV Light; and data collection & analysis software. The provision of sub-contracted and ETO sterilization processing service.

Diseño, desarrollo, fabricación, distribución y mantenimiento de sistemas de recogida de sangre automatizados, sistemas de procesamiento de células sanguíneas y sistemas de aféresis; sistemas de almacenamiento, reducción de agentes patógenos e inactivación de leucocitos en componentes sanguíneos por medio de riboflavina y luz UV, así como software de análisis y recopilación de datos. La prestación de servicios de subcontratación y de esterilización con óxido de etileno.



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This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory. To be read in conjunction with the scope above or the attached appendix.

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: **FM 30402**

| 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 and apheresis systems. The provision of sub-contract and ethylene oxide sterilization processing service. |
| Terumo BCT Europe NV Ikaroslaan 41 Zaventem B-1930 Belgium | The sales, marketing, customer services and logistics for automated blood cell separators and processor equipment, including servicing and associated sterile devices. The provision of technical, regulatory and clinical support for products to be sold in this region. |
| Terumo BCT Italia Srl. Via Simone Martini, 143/145 Roma (RM) 00142 Italy | The Sales, Marketing, Installation and Servicing of automated blood collection systems, blood cell processor systems and apheresis systems including associated sterile single use devices. |
| Terumo BCT Europe NV Romeinsestraat 8 Leuven B-3001 Belgium | Design, development, manufacture, distribution, installation and servicing of active Medical Devices, Laboratory equipment, and accessories for use in Transfusion Medicine. Design, development, manufacture, distribution, installation and servicing of Terumo active Medical Devices and laboratory equipment such as automated surgical instruments, interventional cardiology devices, diabetes devices and general hospital products. |
| TERUMO BCT PORTUGAL, UNIPessoal LDA Rua General Firmino Miguel, nº 3, Torre 2, 12º São Domingos de Benfca Lisboa 1600 100 Portugal | Commercialization for equipment and consumables for blood processing and apheresis procedures. |
| TERUMO BCT POLSKA Sp. z o.o. ul. Hutnicza 14 Katowice 40-241 Poland | Distribution and servicing of automated blood collection systems, blood cell processor systems and apheresis systems. |
| Terumo BCT Tibbi Cihazlar Dagitm ve Hizmetleri A.S. Yenisehir, Aral SK. No:14/A, Atashir Istanbul 34779 Turkey | The sales, marketing, customer services and logistics for automated blood cell separators and processor equipment, including servicing and associated sterile devices. The provision of technical, regulatory and clinical support for products to be sold in this region. |

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| Location | Registered Activities |
|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| Terumo BCT España Sociedad Limitada Calle Velazquez, 78 4D Madrid 28001 Spain | Commercialization and technical service for equipment and consumables for blood processing and apheresis procedures. |
| Terumo BCT España Sociedad Limitada C/ Aragón, 264 - 3º 2ª N.I.F.: W0021849E Barcelona 08007 Spain | Commercialization and technical service for equipment and consumables for blood processing and apheresis procedures. |



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