By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00326**

Issued To: **Terumo BCT Inc.**
10811 W. Collins Ave.
Lakewood
Colorado
80215
USA

Epifanis Alexandros Nikolaos

Digitally signed by Epifanis Alexandros Nikolaos
Date: 2023.11.06 14:24:27 +02'00'

In respect of:

Design, development and manufacture of automated blood cell separators including related medical device management software, cell processor equipment and associated sterile devices, including anticoagulants and preservation solutions used in the collection, processing, and storage of blood and blood components; and systems for storage, pathogen reduction and WBC inactivation of Blood and Blood Components using Riboflavin and UV light.
Those aspects of Annex II related to metrology in the design and manufacturing of T-RAC II.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **1994-11-25** Date: **2020-02-01** Expiry Date: **2024-05-26**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00326**
Date:	**2020-02-01**
Issued To:	**Terumo BCT Inc.** **10811 W. Collins Ave.** **Lakewood** **Colorado** **80215** **USA**

Subcontractor:	**Service(s) supplied**
Evergreen Research, Inc. 433 Park Point Drive, Suite 140 Golden Colorado 80401 USA	**Design** **Manufacture**
Harmac Medical Products IDA Buisness Park Castlerea Co. Rosommon Ireland	**Control of Sterilization** **Manufacture**
Isomedix Operations, Inc. 9120 South 150 East Sandy Utah 84070 USA	**Radiation (Gamma Sterilization)**

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 2072 Southport Road Spartanburg South Carolina 29306 USA	**ETO Sterilization**
OriGen Biomedical, Inc. 7000 Burleson Road Austin Texas 78744 USA	**Control of Sterilization** **Manufacture**
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit Rechain Avenue Andre Ernst 21 Verviers B-4800 Belgium	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 3125 Wichita Court Fort Worth Texas 76140 USA	**Radiation (Gamma Sterilization)**
Synergy Health AST, SRL B13.1 Street 4, Avenue 1 El Coyol Free Zone El Coyol Alajuela 20102 Costa Rica	**ETO Sterilization**
Terumo BCT Europe NV Ikaroslaan 41 1930 Zaventem Belgium	**EU Representative**

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Subcontractor:	**Service(s) supplied**
Terumo BCT Europe NV Romeinsestraat 8 B-3001 Leuven Belgium	**Manufacture**
Terumo BCT Ltd. Old Belfast Road Millbrook Larne BT40 2SH United Kingdom	**Design** **Manufacture** **Moist Heat Sterilization** **Packaging**
Terumo BCT Vietnam Co., Ltd. Long Duc Industrial Park Long Duc Commune Long Thanh District Dong Nai Province Vietnam	**Design** **Manufacture**

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Subcontractor:	**Service(s) supplied**
TFB Manufacturing SRL Calle 58, Zona Franca La Lima Planta de Terumo BCT - Calle Duan y Avenida Turrialba La Lima, Guadalupe 30106 Cartago Costa Rica	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00326**

Date: **2020-02-01**

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Date	Reference Number	Action
25 November 1994		First Issue.
29 June 2000		Change of name, minor change to wording of scope, addition of Gambro BCT Ltd as a sub-contractor.
29 July 2003		Minor scope change addition of "associated" sterile devices, five year renewal, reissue in new format.
11 July 2008	7229654	Company name change, removal of subcontractor Gambro BCT, Quedgeley and certificate renewal.
01 March 2011	7651901	Extension to scope to include anticoagulants and preservation solutions. The addition of CaridianBCT Northern Ireland Ltd to the list of significant subcontractors for design, manufacture, packaging and sterilization. The addition of CaridianBCT Europe NV/SA as the EU Representative.
07 March 2012	7794282	Change of name from CaridianBCT Inc to TerumoBCT, Inc.
13 June 2012	7842952	Addition of STERIS Isomedix Services and Sterigenics Belgium (Petit-Rechain) SA as significant subcontractors for sterilization. The addition of Medistad Medical B.V as significant subcontractor for sterile manufacture.
06 July 2012	7844445	Extension to scope to include, 'systems for storage, pathogen reduction and WBC Inactivation of Blood Components using Riboflavin and UV light'.
9 November 2012	7857296	Extension to scope to include for automated blood cell separators the related management medical device software.

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Date	Reference Number	Action
25 March 2013	7972942	Addition of 'Terumo BCT Europe N.V. Leuven, Belgium' to the list of significant subcontractors for Design and Manufacture. Addition of the line, 'Those aspects of Annex II related to metrology in the design and manufacturing of T-RAC II' to the scope.
17 July 2013	7947389	Certificate renewal. Change from Sterigenics International, LLC, Oak Brook, Illinois to Sterigenics in Belgium in the list of significant subcontractors.
17 December 2013	8083887	Addition of subcontractor 'Harmac Medical Products, IDA Business Park, Castlerea, Co. Roscommon, Ireland'. Change of scope to specify 'blood and blood components'.
28 January 2015	8283477	Addition of subcontractor Harvest Technologies Corp, Plymouth, Massachusetts for service of Sterile Manufacture.
10 February 2016	8468369	Addition of Terumo BCT Vietnam Co., Ltd as significant subcontractor for sterile manufacture. Removal of Harvest Technologies Corp, Plymouth, Massachusetts as significant subcontractor for Sterile Manufacture.
05 January 2017	8621848	Addition of Evergreen Research, Inc. as significant subcontractor for Design and Manufacture. Addition of OriGen Biomedical, Inc. as significant subcontractor for Control of Sterilization and Manufacture. Addition of Sterigenics US, LLC, of Fort Worth, Texas as significant subcontractor for Sterilization services.
19 September 2017	8710139	Certificate re-issue due to address amendments for subcontractors Terumo BCT Ltd and Terumo BCT Vietnam Co., Ltd.

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Date	Reference Number	Action
20 July 2018	8904863	Certificate renewal. Removal of the subcontractor Medistad Medical B.V. Specification of the sterilisation method provided by significant subcontractors with activity of Sterilization. Rewording of the subcontracted activity of "Sterile manufacture" to "Control of sterilization" and "Manufacture".
27 February 2019	7781664	Traceable to NB 0086.
23 October 2019	9768816	Renewal. Modified subcontractor name from "Steris Corp Isomedix Services" to "Isomedix Operations, Inc." to match the ISO certificate.
Current	3106024	Added subcontractor Isomedix Operations, Inc. South Carolina site.

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
13 October 2021	3538608	Removal of Design from Terumo BCT Europe NV, Leuven Activities. Correction and clarification that the certificate scope includes those aspects of Annex II concerned with securing and maintaining sterile conditions of automated blood cell separator waste bags. Correction and clarification that the certificate scope includes those aspects of Annex II concerned with the metrological requirements of automated blood collection accessories.
23 December 2021	3596551	Addition of subcontractors TFB Manufacturing SRL, and Synergy Health AST, SRL.
31 January 2022	3624074	Administrative correction to remove "Design" from the activities performed by subcontractor Terumo BCT Europe NV, Leuven, which was previously removed under Reference Number 3538608.
07 March 2022	3639849	Administrative correction: Addition of subcontractors TFB Manufacturing SRL, which was previously added under Reference Number 3596551.

Inspiring trust for a more resilient world.

07 March 2022

Terumo BCT Inc.
10811 W. Collins Ave.
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 00326	93/42/EEC Annex II excluding Section 4	3639849	Administrative correction: Addition of subcontractors TFB Manufacturing SRL, which was previously added under Reference Number 3596551.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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