By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 584795**

Issued To: **Terumo Cardiovascular Systems Corporation**
125 Blue Ball Rd
Elkton
Maryland
21921
USA

In respect of:

Design, Development and Manufacture of Sterile Blood Oxygenators, Centrifugal Pumps, Arterial Filters, Cardioplegia Delivery Sets, Pressure Relief Valves, CDI Cuvettes, CDI Shunt Sensors, CDI Calibration Gases, Blood Reservoirs, Endoscopic Vessel Harvesting Systems, Devices for heart stabilization and positioning for use in open heart surgery, and associated sterile and non-sterile accessories.

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):

Albert Roossien, Regulatory Lead

First Issued: **2012-05-31** Date: **2019-02-13** Expiry Date: **2022-02-22**

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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 584795**
Date:	**2019-02-13**
Issued To:	**Terumo Cardiovascular Systems Corporation** **125 Blue Ball Rd** **Elkton** **Maryland** **21921** **USA**

Subcontractor:	**Service(s) supplied**
Aomori Olympus Co., Ltd 2-248-1, Okkonoki Kuroishi-Shi AOMORI 036-0357 Japan	**Manufacture**
Indo-US MIM Tec Pvt. Ltd Plot #45 (P) KIADB Industrial Area Hoskote Banglore Karnataka 562 114 India	**Manufacture**
Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg Deutschland Germany	**Manufacture**

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Issued To:	**Terumo Cardiovascular Systems Corporation** **125 Blue Ball Rd** **Elkton** **Maryland** **21921** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 2311 Lincoln Avenue Hayward California 94545 USA	**Gamma Sterilization**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**

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Issued To:	**Terumo Cardiovascular Systems Corporation** **125 Blue Ball Rd** **Elkton** **Maryland** **21921** **USA**

Subcontractor:	**Service(s) supplied**
Surmodics, Inc. 9924 West 74th Street Eden Prairie Minnesota 55344 USA	**Crucial Supplier**
Terumo Cardiovascular Systems Corp. 6200 Jackson Road Ann Arbor Michigan 48103 USA	**Design** **Development**
Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium	**EU Representative**
Terumo Medical Corporation 950 Elkton Road Elkton MD 21921 USA	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 584795**

Date: **2019-02-13**

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Date	Reference Number	Action
31 May 2012	7805751	First issue. Transfer from another Notified Body.
14 August 2014	8180239	Extend scope to include devices for heart stabilization and positioning for use in open heart surgery; Remove "Cardiovascular Procedure Kits" from Scope. Add subcontractors relevant to heart stabilization and positioning devices: ARMM,Inc., Indo-US MIM Tec Pvt. Ltd., and Sterigenics Hayward, and Corona sites.
29 May 2015	8184532	Scope updated from "Endoscopic Vein Harvesting Systems" to "Endoscopic Vessel Harvesting Systems".
09 February 2017	8630231	Certificate renewal. Word 'sterile' added to scope. Crucial supplier SurModics added. Significant subcontractors ARMM Inc in California USA, Sterigenics US LLC in New Jersey USA and Sterigenics in NC USA removed. Administrative changes.
Current	7843590	Traceable to NB 0086.