

EC Certificate - Full Quality Assurance System

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

No.**CE 664635****Issued To:**

**Terumo Medical Corporation
265 Davidson Avenue, Suite 320
Somerset
New Jersey
08873
USA**

In respect of:

Design, development and manufacture of sterile vascular closure devices

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: **2017-01-20**

Date: **2019-07-18**

Expiry Date: **2022-01-19**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

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

Certificate No: **CE 664635**
 Date: **2019-07-18**
 Issued To: **Terumo Medical Corporation**
265 Davidson Avenue, Suite 320
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USA

Subcontractor:

Service(s) supplied

DSM Biomedical
 735 Pennsylvania Drive
 Exton
 PA 19341
 USA

Animal Tissues / Derivatives

St. Jude Medical
 14901 DeVeau Place
 Minnetonka
 Minnesota
 55345-2126
 USA

Manufacture

St. Jude Medical Costa Rica Ltda.
 Edificio #44, Calle 0, Ave. 2
 Zona Franca
 El Coyo, Alajuela
 Costa Rica

Manufacture

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 1700 College Boulevard West Memphis AR 72301 USA	Gamma Sterilization
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	Gamma Sterilization
Synergy Health AST SRL B13.1 Street 4, Avenue 1 El Coyoil Free Zone 20102 El Coyoil Alajuela Costa Rica	ETO Sterilization

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Subcontractor:

Service(s) supplied

Terumo Europe, N.V.
 Interleuvenlann 40, B-3001
 Leuven
 Belgium

EU Representative

Terumo Puerto Rico LLC
 Innovation Street Lot 21
 Caguas West Industrial Park
 Caguas
 00725
 Puerto Rico

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Certificate History

Certificate No: **CE 664635**
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Date	Reference Number	Action
20 January 2017	8645594	First issue.
20 October 2017	8794520	Update name and address of subcontractor Terumo Puerto Rico LLC.
27 February 2019	8798156	Traceable to NB 0086.
Current	9659326	Change in legal manufacturer address Updated address of Terumo Puerto Rico LLC to align with BSI ISO certificates.

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.