

# 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**

...making excellence a habit.™

Page 1 of 1

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.

# EC Certificate - Full Quality Assurance System

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 664635**  
 Date: **2019-07-18**  
 Issued To: **Terumo Medical Corporation**  
**265 Davidson Avenue, Suite 320**  
**Somerset**  
**New Jersey**  
**08873**  
**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**

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System

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 664635**  
 Date: **2019-07-18**  
 Issued To: **Terumo Medical Corporation**  
**265 Davidson Avenue, Suite 320**  
**Somerset**  
**New Jersey**  
**08873**  
**USA**

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 Coyo Free Zone 20102 El Coyo Alajuela Costa Rica	ETO Sterilization

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System

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 664635**  
 Date: **2019-07-18**  
 Issued To: **Terumo Medical Corporation**  
**265 Davidson Avenue, Suite 320**  
**Somerset**  
**New Jersey**  
**08873**  
**USA**

### 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

**Manufacture**

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 664635**  
Date: **2019-07-18**  
Issued To: **Terumo Medical Corporation**  
**265 Davidson Avenue, Suite 320**  
**Somerset**  
**New Jersey**  
**08873**  
**USA**

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.

...making excellence a habit.™

Page 1 of 1

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.

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.