

# 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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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:

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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 Coyol, 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 Coyol Free Zone  
20102 El Coyol  
Alajuela  
Costa Rica

**ETO Sterilization**

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**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**

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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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