

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:

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 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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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**
Date: **2019-07-18**
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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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