



By Royal Charter

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.TM

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 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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Service(s) supplied

Terumo Europe, N.V.
Interleuvenlaan 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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EC Certificate - Full Quality Assurance System Certificate History

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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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Page 1 of 1

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