

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:

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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 Coyal Free Zone 20102 El Coyal 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

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.