

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Terumo Puerto Rico LLC
Innovation Street Lot 21
Caguas West Industrial Park
Caguas
00725
Puerto Rico


Holds Certificate No:

FM 670625

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacturing and distribution of Vascular Closure Devices.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2017-07-20

Latest Revision Date: 2018-07-12

Effective Date: 2017-07-20

Expiry Date: 2020-07-19

Page: 1 of 1



...making excellence a habit.™



TMC - Declaration of Conformity

Terumo Medical Corporation (TMC) hereby declares that the following TMC facilities and products are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 11.1 (a) of the Directive, relating to the "Full Quality Assurance System" set out in Annex II, and by certification of Annex II.3 and Annex II.4 under the supervision of BSI as Notified Body. All supporting documentation is retained under the premises of TMC. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer.

Legal Manufacturer Address: Terumo Medical Corporation
2101 Cottontail Lane, Somerset, NJ 08873 USA

European Representative: Terumo Europe, N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Product Type: Vascular Closure Device

Product Name(s) and Model Number(s): **Angio-Seal STS Plus Vascular Closure Device**
(610120, 610122)
Angio-Seal VIP Vascular Closure Device
(610132, 610133)
Angio-Seal Evolution Vascular Closure Device
(C610136, C610137)

Classification: Class III per Annex IX of the MDD 93/42/EEC, Rules 8 and 17

GMDN Code(s): 60710 - Femoral artery compression plug, collagen

EC Certificate No and Expiration Date: Certificate Annex II No: CE 664635 (Expiration: 19 January 2022)
Certificate Annex II.4 No: CE 664636 (Expiration: 19 January 2022)

Applicable Quality System Standards: ISO 13485: 2003
EN ISO 13485: 2012

Notified Body: BSI, Kitemark Court, Davy Avenue, Knowlhill
Milton Keynes MK5 8PP United Kingdom

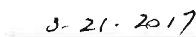
Notified Body Number: 0086

Signature:



Kathleen Little
VP of Quality and Regulatory Affairs

Issue Date:



Issue Date

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

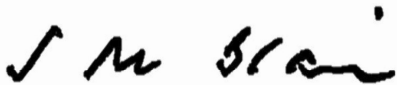
No. CE 664635
Issued To: **Terumo Medical Corporation**
2101 Cottontail Lane
Somerset
New Jersey
08873
USA

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2017-01-20**

Date: **2017-10-20**

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: **2017-10-20**
 Issued To: **Terumo Medical Corporation**
2101 Cottontail Lane
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

...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: **2017-10-20**
 Issued To: **Terumo Medical Corporation**
2101 Cottontail Lane
Somerset
New Jersey
08873
USA

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	Gamma Sterilization
Sterigenics US, LLC 1700 College Boulevard West Memphis AR 72301 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

...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: **2017-10-20**
 Issued To: **Terumo Medical Corporation**
2101 Cottontail Lane
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
 Caguas West Industrial Park
 Lot 21 B Street
 Puerto Rico
 00725
 USA

Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 664635**
 Date: **2017-10-20**
 Issued To: **Terumo Medical Corporation**
2101 Cottontail Lane
Somerset
New Jersey
08873
USA

Date	Reference Number	Action
20 January 2017	8645594	First issue.
Current	8794520	Update name and address of subcontractor Terumo Puerto Rico LLC.

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. CE 664636
Issued To: **Terumo Medical Corporation**
2101 Cottontail Lane
Somerset
New Jersey
08873
USA

In respect of:

Angio-Seal Vascular Closure Devices

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC Annex II Section 4 and Regulation 722/2012. The design conforms to the requirements of this directive and regulation. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **20 January 2017**

Date: **20 January 2017**

Expiry Date: **19 January 2022**

...making excellence a habit.™

Page 1 of 3

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 certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 664636

Issued To:

Terumo Medical Corporation
2101 Cottontail Lane
Somerset
New Jersey
08873
USA

Angio-Seal Vascular Closure Device

Model Number	Description
610120	6F Angio-Seal STS-Plus
610122	8F Angio-Seal STS-Plus
610132	6F Angio-Seal VIP
610133	8F Angio-Seal VIP
C610136	6F Angio-Seal Evolution
C610137	8F Angio-Seal Evolution

First Issued: **20 January 2017**

Date: **20 January 2017**

Expiry Date: **19 January 2022**

...making excellence a habit.™

Page 2 of 3

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 certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 664636

Issued To:

**Terumo Medical Corporation
2101 Cottontail Lane
Somerset
New Jersey
08873
USA**

Certificate History

Date	Reference Number	Action
20 January 2017	10167452	First Issue.



First Issued: **20 January 2017**

Date: **20 January 2017**

Expiry Date: **19 January 2022**

...making excellence a habit.™