bsi.

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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
Effective Date: 2017-07-20
Latest Revision Date: 2018-07-12
Expiry Date: 2020-07-19

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Digitally signed by Grabazei Alexandru
Date: 2019.03.28 20:15:25 EET
Reason: MoldSign Signature
Location: Moldova

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:

3. 21. 2017
Issue Date

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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**

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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**

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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**

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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**

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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.

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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**

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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**

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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**

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