

# EC Design-Examination Certificate

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

**No.** **CE 664636**

Issued To:

**Terumo Medical Corporation**  
**265 Davidson Avenue, Suite 320**  
**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 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.<sup>TM</sup>

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780  
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.  
A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 664636

Issued To:

**Terumo Medical Corporation**  
**265 Davidson Avenue, Suite 320**  
**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: **2017-01-20**

Date: **2019-07-18**

Expiry Date: **2022-01-19**

...making excellence a habit.<sup>TM</sup>

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780  
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.  
A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 664636

Issued To:

**Terumo Medical Corporation**  
**265 Davidson Avenue, Suite 320**  
**Somerset**  
**New Jersey**  
**08873**  
**USA**

## Certificate History

Date	Reference Number	Action
20 January 2017	10167452	First Issue.
27 February 2019	8798156	Traceable to NB 0086.
Current	9659425	Change in legal manufacturer address.

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

Date: **2019-07-18**

Expiry Date: **2022-01-19**

...making excellence a habit.™

Page 3 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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780  
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.  
A member of BSI Group of Companies.