

EC Design-Examination Certificate

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

No.**CE 664637****Issued To:**

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

In respect of:**Femoseal Vascular Closure System**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. 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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

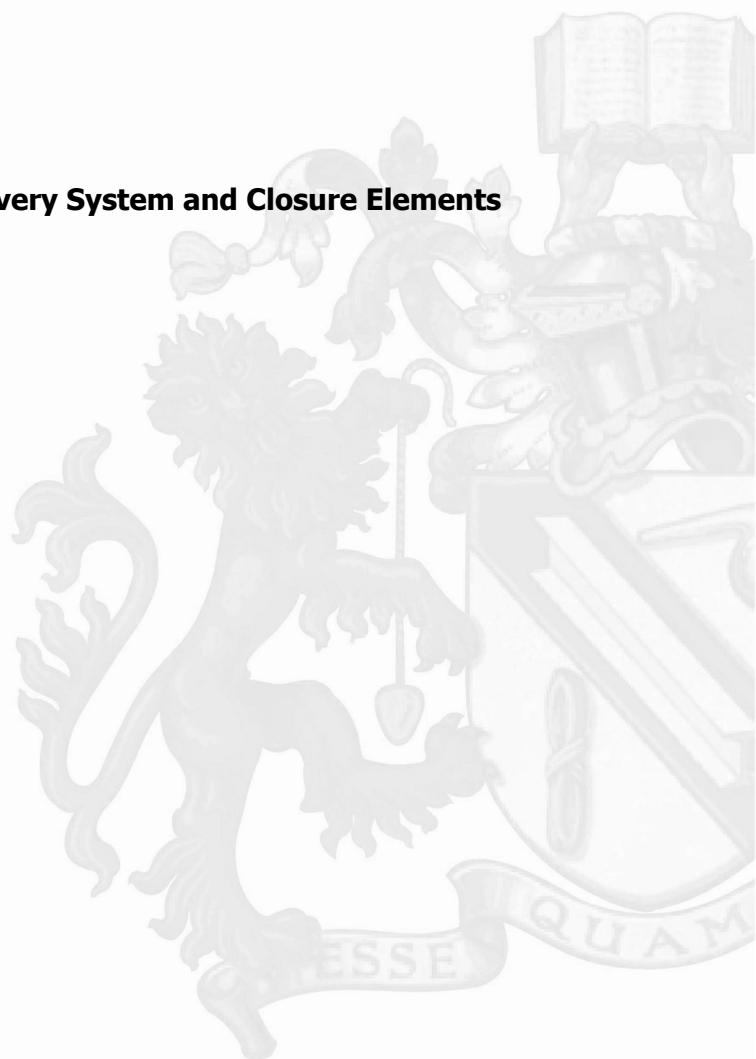
EC Design-Examination Certificate

Supplementary Information to CE 664637

Issued To:

Terumo Medical Corporation
2101 Cottontail Lane
Somerset
New Jersey
08873
USA

FemoSeal Vascular Closure System, including Delivery System and Closure Elements
Model Number C11202

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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 664637

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.™

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.