bsi.

By Royal Charter

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**

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EC Design-Examination Certificate

Supplementary Information to CE 664636

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265 Davidson Avenue, Suite 320
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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**

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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**

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