By Royal Charter

EC Design-Examination Certificate

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

No. **CE 518026**

Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

In respect of:

RX Accunet Embolic Protection Systems (Class III)

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: **27 June 2007** Date: **12 January 2016** Expiry Date: **01 November 2017**

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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: + 44 845 080 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.

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Supplementary Information to CE 518026

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Product: Embolic Protection Systems

Description	Catalogue Number
RX ACCUNET, 4.5 mm, 190 cm	1010134-45
RX ACCUNET, 5.5 mm, 190 cm	1010134-55
RX ACCUNET, 6.5 mm, 190 cm	1010134-65
RX ACCUNET, 7.5 mm, 190 cm	1010134-75
RX ACCUNET, 4.5 mm, 300 cm	1010135-45
RX ACCUNET, 5.5 mm, 300 cm	1010135-55
RX ACCUNET, 6.5 mm, 300 cm	1010135-65
RX ACCUNET, 7.5 mm, 300 cm	1010135-75
RX ACCUNET (3:1), 4.5 mm, 190 cm	1011651-45
RX ACCUNET (3:1), 5.5 mm, 190 cm	1011651-55
RX ACCUNET (3:1), 6.5 mm, 190 cm	1011651-65
RX ACCUNET (3:1), 7.5 mm, 190 cm	1011651-75
RX ACCUNET (3:1), 4.5 mm, 300 cm	1011652-45
RX ACCUNET (3:1), 5.5 mm, 300 cm	1011652-55
RX ACCUNET (3:1), 6.5 mm, 300 cm	1011652-65
RX ACCUNET (3:1), 7.5 mm, 300 cm	1011652-75

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Certificate History

Date	Reference Number	Action
27 June 2007	10088272	First Issue, transfer from KEMA
21 November 2007	10092624	Certificate Renewal
19 December 2008	10100900	Review of mold release change in the resin used to manufacture the flushing tool
20 February 2009	10102942	Remove Business Unit name (Vascular Solutions) from the certificate
12 September 2012	10136292	Addition of alternative Teflon Coating. Correction of typographical errors.
24 October 2012	10137348	Certificate Renewal
28 July 2014	10148573	Review of specification change to automated testing method of sheath peel-away force.
05 October 2015	10158710	Change review to assess the impact of the Loctite 648 reformulation.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.

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