By Royal Charter

EC Design-Examination Certificate

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

No. **CE 518027**

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

In respect of:

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

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Supplementary Information to CE 518027

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Product: Carotid Stenting System

RX Acculink Straight

Catalogue Number	Stent Diameter	Stent Length
1010126-20	5.0	20
1010127-20	6.0	20
1010128-20	7.0	20
1010129-20	8.0	20
1010130-20	9.0	20
1010131-20	10.0	20
1010126-30	5.0	30
1010127-30	6.0	30
1010128-30	7.0	30
1010129-30	8.0	30
1010130-30	9.0	30
1010131-30	10.0	30
1010126-40	5.0	40
1010127-40	6.0	40
1010128-40	7.0	40
1010129-40	8.0	40
1010130-40	9.0	40
1010131-40	10.0	40

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RX Acculink Tapered

Catalogue Number	Stent Diameter	Stent Length
1010132-30	6.0 – 8.0	30
1010133-30	7.0 – 10.0	30
1010132-40	6.0 – 8.0	40
1010133-40	7.0 – 10.0	40

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Certificate History

Date	Reference Number	Action
27 June 2007	10088274	First Issue, Transfer from KEMA
03 October 2007	10091556	Change Acculink Tapered catalogue number 1006881-40 to 1006861-30
21 November 2007	10092625	Certificate Renewal
20 February 2009	10102942	Remove Business Unit name (Vascular Solutions) from the certificate
26 September 2012	10134045	Indication Change to include standard risk patients.
09 October 2012	10137242	Certificate Renewal and Removal of the Acculink OTW Straight and Acculink OTW Tapered Catalogue Numbers from the certificate.
20 March 2013	10140704	Design and manufacturing process change to inner member.
30 September 2014	10149810	Change to visual inspection criteria for bent struts.
13 May 2015	10155215	Introduction of electronic IFUs in compliance with Regulation 207/2012.
11 June 2015	10156121	Changes to hypotube supplier, on-line hypotube inspection, finished product tensile method, and process monitoring specification.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.

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