By Royal Charter

EC Design-Examination Certificate

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

No. **CE 503252**

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

In respect of:

X.ACT Carotid Stent 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: **19 January 2006** Date: **12 January 2016** Expiry Date: **18 January 2021**

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Supplementary Information to CE 503252

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Product: X.ACT Carotid Stent System

Catalogue No.	Configuration	Length (mm)	Diameter (mm)
XRX 020 07S	Straight	20	7
XRX 020 08S	Straight	20	8
XRX 020 09S	Straight	20	9
XRX 020 10S	Straight	20	10
XRX 030 07S	Straight	30	7
XRX 030 08S	Straight	30	8
XRX 030 09S	Straight	30	9
XRX 030 10S	Straight	30	10
XRX 030 08T	Tapered	30	8-6
XRX 030 09T	Tapered	30	9-7
XRX 030 10T	Tapered	30	10-8
XRX 040 08T	Tapered	40	8-6
XRX 040 09T	Tapered	40	9-7
XRX 040 10T	Tapered	40	10-8

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Certificate History

Date	Reference Number	Action
19 January 2006	10075873	Transfer from another Notified Body
01 February 2007	10082913	Changes to the handle components of the Xact Carotid Stent System delivery system
26 February 2009	10103026	Update the manufacturer's name and address, change the sterilization site to Sterigenics, CA, change the manufacturing location from Abbott Ireland Vascular Division in Galway Ireland to Abbott Vascular, Temecular, CA and review minor product changes.
08 December 2010	10119194	Certificate Renewal for five year period
26 September 2012	10134045	Indication Change to include standard risk patients. Branding change to replace "Xact" with "X.ACT".
13 May 2015	10155215	Introduction of electronic IFUs in compliance with Regulation 207/2012.
29 October 2015	10158830	Certificate Renewal for five year period
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.

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