By Royal Charter

EC Design-Examination Certificate

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

No. **CE 553292**

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

In respect of:

HI-TORQUE® PROGRESS PTCA Guide Wires

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):

Gary Fenton, Global Assurance Director

First Issued: **14 September 2009** Date: **21 August 2014** Expiry Date: **13 September 2019**

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Supplementary Information to CE 553292

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Product: HI-TORQUE® PROGRESS PTCA Guide Wires

Catalogue Number	Wire Diameter	Wire Length
1011836	0.014″	190 cm
1011837	0.014″	300 cm
1011838	0.014″	190 cm
1011839	0.014″	300 cm
1011840	0.014″	190 cm
1011841	0.014″	300 cm
1011842	0.014″	190 cm
1011843	0.014″	300 cm
1011844	0.014″	190 cm
1011845	0.014″	300 cm

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Certificate History

Date	Reference Number	Action
14 September 2009	10109294	First issue
12 September 2012	10136292	Addition of alternative Teflon Coating.
04 October 2012	10137228	Addition of Abbott Vascular manufacturing site in Barceloneta, Puerto Rico
16 April 2013	10141111	Expand the indications for use to include chronic total occlusions.
07 June 2013	10141132	Addition of Synergy Health-Tullamore, Ireland as a qualified sterilizatiion site.
02 July 2013	10142172	Addition of AIOx/Foil peel-able pouch as alternate
21 August 2014	10146756	Certificate renewal

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