By Royal Charter

EC Design-Examination Certificate

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

No. **CE 592549**

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

In respect of:

GRAFTMASTER RX Coronary Stent Graft 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: **21 December 2012** Date: **12 January 2016** Expiry Date: **20 December 2017**

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Supplementary Information to CE 592549

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Graftmaster RX Catalog Numbers				
Balloon Diameter	**Catalog Number**	**Stent Length**		
(mm)		**16mm**	**19mm**	**26mm**
2.80	1012817	-16	-19	-26
3.50	1012818	-16	-19	-26
4.00	1012819	-16	-19	-26
4.50	1012820	-16	-19	-26
4.80	1012821	-16	-19	-26

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Certificate History

Date	Reference Number	Action
21 December 2012	10137649	First Issue.
03 July 2013	10142390	Additional ETO sterilisation chamber at Sligo facility.
14 November 2013	10143388	Addition of laser welding manufacturing process in Abbott Vascular Clonmel facility.
03 December 2014	10152809	Clarification to labeling symbols
13 May 2015	10155215	Introduction of electronic IFUs in compliance with Regulation 207/2012.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.

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