Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA 95054

Tel: 408-845-3000
Fax: 408-845-3333

DECLARATION OF CONFORMITY

Manufacturer:	Abbott Vascular
Address:	3200 Lakeside Drive Santa Clara, California 95054 USA
Additional Manufacturing Sites:	Cashel Road Clonmel, County Tipperary Ireland
Device Name:	**GRAFTMASTER RX Coronary Stent Graft System**
Device Classification:	Class III
GMDN Code:	53616 – Bare-metal coronary artery stent
Classification Rationale:	The following Annex IX definition(s) apply to the **GRAFTMASTER RX Coronary Stent Graft System** for purposes of classifications: Per Rule 8, Annex IX, all implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended: to be used in direct contact with the heart, the central circulatory system, or the central nervous system, in which case they are in Class III.
Authorized European Representative:	Abbott Vascular International BVBA Park Lane Culliganlaan. 2B 1831 Diegem, Belgium

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Model Numbers:

GRAFTMASTER RX Coronary Stent Graft System			
Balloon Diameter (mm)	**Stent Length**		
	16mm	**19mm**	**26mm**
2.80	1012817-16	1012817-19	1012817-26
3.50	1012818-16	1012818-19	1012818-26
4.00	1012819-16	1012819-19	1012819-26
4.50	1012820-16	1012820-19	1012820-26
4.80	1012821-16	1012821-19	1012821-26

I, the undersigned, hereby declare that the medical devices specified above conform to the applicable Essential Requirements listed in Annex I and Annex II of EC Council Directive 93/42/EEC.

This declaration is supported by an EC quality system and EC design examination approval listed below.

Supporting Certificates:

- EC Quality Management System, ISO 13485:2003 (Santa Clara) Certificate Number: FM72377
- Quality Management System, ISO 13485:2003 (Ireland), Certificate Number: MD 509832
- EC Design Examination Certificate Number: CE 592549
- EC Full Quality Assurance Certificate Number: CE 510108

Notified Body: British Standards Institution, a notified body authorized by the United Kingdom Competent Authority, Notified Body Identification Number 0086.

This Declaration of Conformity is valid until revision or with the obsolescence of any of the supporting certificates listed above.

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This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

By: Susan Slane

Susan Slane
Divisional VP, Global Quality and Compliance
Abbott Vascular

Place of issue: _____ Date of issue: 11/18/13

Effective Date: 11/18/13