

## ***DECLARATION OF CONFORMITY***

**Manufacturer:** Abbott Vascular

**Address:** 3200 Lakeside Drive  
Santa Clara, California 95054 USA

**Additional  
Manufacturing Sites:** Cashel Road  
Clonmel, County Tipperary  
Ireland

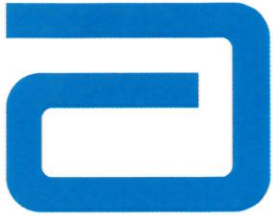
**Device Name:** **GRAFTMASTER RX Coronary Stent Graft System**

**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



**Model Numbers:**

<b>GRAFTMASTER RX Coronary Stent Graft System</b>			
<b>Balloon Diameter (mm)</b>	<b>Stent Length</b>		
	<b>16mm</b>	<b>19mm</b>	<b>26mm</b>
<b>2.80</b>	1012817-16	1012817-19	1012817-26
<b>3.50</b>	1012818-16	1012818-19	1012818-26
<b>4.00</b>	1012819-16	1012819-19	1012819-26
<b>4.50</b>	1012820-16	1012820-19	1012820-26
<b>4.80</b>	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.

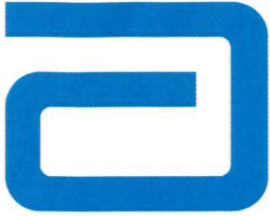
This declaration is supported by an EC quality system and EC design examination approval listed below.

**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.



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