

**DECLARATION OF CONFORMITY**

**Manufacturer:** Abbott Vascular

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

**Additional  
Manufacturing Sites:** 26531 Ynez Road  
Temecula, California 92591, USA

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Building PR-17, Road #2 km. 58.0  
Cruce Davilla  
Barceloneta 00617, Puerto Rico

**Device Name:** **HI-TORQUE® BALANCE 0.014” Guide Wire**

**Device Classification:** Class III

**GMDN Code:** 35094, Catheter guide wire

**Classification Rationale:** The following Annex IX definition(s) apply to the **HI-TORQUE® BALANCE 0.014” Guide Wire** for purposes of classifications: Per Rule 6, Annex IX, all surgically invasive devices intended for transient use are in Class IIa unless they are: Intended specifically to control, diagnose, monitor, or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III.

**Authorized European  
Representative:** Abbott Vascular International BVBA  
Park Lane  
Culliganlaan 2B  
1831 Diegem, Belgium

**Model Numbers:** **HI-TORQUE® BALANCE 0.014” Guide Wire**

2800X	Straight Tip Shape
2800XJ	‘J’ Tip Shape
2810X	Straight Tip Shape
2810XJ	‘J’ Tip Shape

I, the undersigned, hereby declare that the medical devices specified above conform with 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 design examination approval listed below.

Quality Management System - ISO 13485:2003, Certificate: FM72377, FM510125  
EC Design Examination Certificate: CE 01497  
Full Quality Assurance Certificate: CE 510108

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

British Standards Institution  
Kitemark Court  
Davy Avenue  
Knowlhill  
Milton Keynes  
MK5 8PP  
United Kingdom

This Declaration of Conformity expires upon revision or with the revision or expiration of any of the supporting certificates listed above.

By: Sg Slane Date: 6/12/13

Susan Slane  
Divisional VP, Global Quality and Compliance  
Abbott Vascular