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
Manufacturing Sites:	26531 Ynez Road Temecula, California 92591, USA 30590 Cochise Circle Murrieta, California 92563, USA
Device Name:	HI-TORQUE® FLOPPY II 0.014'' EXTRA SUPPORT Guide Wire
Device Classification:	Class III
GMDN Code:	35094 – Cardiac catheter guidewire, single-use
Classification Rationale:	The following Annex IX definition(s) apply to the HI-TORQUE® FLOPPY II 0.014'' EXTRA SUPPORT 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

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Model Numbers: **HI-TORQUE® FLOPPY II 0.014'' EXTRA SUPPORT Guide Wire**

FG#	Tip Shape
2229XM	Straight Tip Shape
2229XM-XXX	Straight Tip Shape
2229XMJ-XXX	'J' Tip Shape
2235XM-XXX	Straight Tip Shape
2235XMJ-XXX	'J' Tip Shape
2239XM	Straight 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 Part 4 of EC Council Directive 93/42/EEC.

Directive 2006/42/EC on Machinery and directive 1989/686/EC on Personal Protective Equipment do not apply.

This declaration is supported by an EC quality system and design examination approval listed below.
Quality Management System - ISO 13485:2003, Certificate: FM72377
EC Design Examination Certificate: CE 01497
Full Quality Assurance Certificate: CE 510108

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.

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

By: Sg Slane Date: 8/15/14

Susan Slane
Divisional VP, Global Quality and Compliance
Abbott Vascular

Place of issue: Temecula Date of issue: 8/15/14

Effective Date: 8/15/14