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:	26531 Ynez Road Temecula, California 92591, USA 30590 Cochise Circle Murrieta, CA, 92563, USA Building PR-17, Road #2 km. 58.0 Cruce Davilla Barceloneta 00617, Puerto Rico
Device Name:	HI-TORQUE® WHISPER™ MS 0.014'' Guide Wire with Hydrophilic Coating
Device Classification:	Class III
Classification Rationale:	The following Annex IX definition(s) apply to the HI-TORQUE® WHISPER™ MS 0.014'' Guide Wire with Hydrophilic Coating 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.
GDMN Code:	35094: catheter guidewires
Authorized European Representative:	Abbott Vascular International BVBA Park Lane Culliganlaan 2B 1831 Diegem, Belgium

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Model Numbers: **HI-TORQUE® WHISPER™ MS 0.014'' Guide Wire with Hydrophilic Coating**

	Device Length	Tip Shape	Radiopaque Length
1005355H	175 cm	Straight	3 cm
1005355HJ	175 cm	'J'	3 cm
1005357H	190 cm	Straight	3 cm
1005357HJ	190 cm	'J'	3 cm
1005359H	300 cm	Straight	3 cm
1005359HJ	300 cm	'J'	3 cm

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 01753
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.

By: Susan Slane Date: 7/10/13

Susan Slane
Divisional VP, Global Quality and Compliance
Abbott Vascular