

DECLARATION OF CONFORMITY

Manufacturer: Abbott Vascular

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

Manufacturing Site: 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 with Hydrocoat Hydrophilic Coating

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 with Hydrocoat 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.

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

**Model Numbers: HI-TORQUE® FLOPPY II® 0.014” EXTRA
SUPPORT Guide Wire with Hydrocoat Hydrophilic
Coating**

FG#	Tip Shape
22X99H	Straight Tip Shape
22XX99H-XXX	Straight Tip Shape
22X99HJ-XXX	‘J’ Tip Shape
223X9H-XXX	Straight Tip Shape
223X9HJ-XXX	‘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.

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 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.

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

By: Susan 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