

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

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

Device Name: HI-TORQUE® BALANCE MIDDLEWEIGHT™ 0.014”
Guide Wire with Hydrocoat Hydrophilic Coating

Device Classification: Class III

GMDN Code: 35094, Catheter guide wire

Classification Rationale: The following Annex IX definition(s) apply to the HI-TORQUE® BALANCE MIDDLEWEIGHT™ 0.014” 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® BALANCE MIDDLEWEIGHT™ 0.014” Guide Wire with Hydrocoat Hydrophilic Coating**

100178X-HC	Straight Tip Shape
100178XJ-HC	‘J’ Tip Shape



3200 Lakeside Drive
Santa Clara, CA 95054

Tel 408-845-3000
Fax 408-845-3333

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: 6/12/13

Susan Slane
Divisional VP, Global Quality and Compliance
Abbott Vascular