

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

Building PR-17, Road #2 km. 58.0

Cruce Davilla

Barceloneta 00617, Puerto Rico

Device Name:

HI-TORQUE

BALANCE

MIDDLEWEIGHT

UNIVERSAL II 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 MIDDLEWEIGHT UNIVERSAL II 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



3200 Lakeside Drive Santa Clara, CA 95054

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

Model Numbers:

HI-TORQUE BALANCE UNIVERSAL II Guide Wire

MIDDLEWEIGHT

1009664	1009664J
1009665	1009665J
1009666	1009666Ј
1009667	1009667J

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 534263 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.

7/10/13
ite:
a

Susan Slane

Divisional VP, Global Quality and Compliance

Abbott Vascular