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
Device Name:	GUIDE WIRE INTRODUCER ACCESSORY KIT with COPILOT™
Manufacturing Sites:	Abbott Vascular 30590 Cochise Circle Murrieta , CA 92563 USA Availmed S.A. de C.V. Av. Paseo Reforma No. 8950 Interior B1, C1, E1, E2, F2, G1 (Local A, B, C, G, H) La Mesa Tijuana, 22116 Mexico
Device Classification:	Class I
GMDN Code:	10678, Catheter introducer
Classification Rationale:	GUIDE WIRE INTRODUCER ACCESSORY KIT with COPILOT™ is a class I device per Rule 1, Annex IX of the Medical Device Directive in that it is not surgically invasive (a device which, in whole or part, penetrates inside the body, either through a body with the aid or in the context of a surgical operation).
Authorized European Representative:	Abbott Vascular International BVBA Park Lane, Culliganlaan 2B 1831 Diegem, Belgium
Model Numbers:	GUIDE WIRE INTRODUCER ACCESSORY KIT with COPILOT™

Part Name/Description	Part Number
GUIDE WIRE INTRODUCER ACCESSORY KIT with COPILOT™	1003330

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I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I and with Annex II (except part 4) of EC Council Directive 93/42/EEC.

This declaration is made in accordance with Annex VII and Annex II (except part 4) of EC Council 93/42/EEC.

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

Supporting Certificates:
Annex II (except part 4), Certificate Number: CE 510108
EC Quality Management System, ISO 13485:2003 Certificate Number: FM 72377 and FM 585026 for the manufacturing location at Availmed, Tijuana, Mexico

Notified Body:
British Standards Institution – Notified Body Identification Number 0086
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MK5 8PP
United Kingdom

This Declaration of Conformity is valid until revision or with the obsolescence of the supporting Annex II certificate listed above.

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

By: SG Slane Date: 12/5/14

Susan Slane
Divisional VP, Global Quality and Compliance
Abbott Vascular

Place of issue: Temecula Date of issue: 12/5/14

Effective Date: 12/5/14