

**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

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

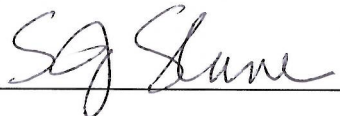
Milton Keynes

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:  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