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

**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 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

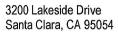
Park Lane, Culliganlaan 2B

1831 Diegem, Belgium

**Model Numbers:** 

GUIDE WIRE INTRODUCER ACCESSORY KIT

Part Name/Description	Part Number
GUIDE WIRE INTRODUCER ACCESSORY KIT /.096"	22295
GUIDE WIRE INTRODUCER ACCESSORY KIT /.115"	22295-115





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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

Version 3.0

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: Same	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:/2/5/14	

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