

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

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: Susan 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