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

Additional Manufacturing Sites: 30590 Cochise Circle
Murrieta, California 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 Name: 20/30 PRIORITY PACK™ Accessory Kit

Device Classification: Class IIa

GMDN Code: 17541, Catheter-balloon inflator, single-use

Classification Rationale: The following Annex IX definition(s) apply to the 20/30 PRIORITY PACK™ Accessory Kit 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

Model Numbers: **20/30 PRIORITY PACK™ Accessory Kit**

Part Name/Description	Part Number
20/30 PRIORITY PACK™ Accessory Kit /.096" RHV	1000186
20/30 PRIORITY PACK™ Accessory Kit /.115" RHV	1000186-115

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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.

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