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 w/ COPILOT® Bleedback Control Valve
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 w/ COPILOT® Bleedback Control Valve 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

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Model Numbers: **20/30 PRIORITY PACK w/ COPILOT® Bleedback Control Valve**

Part Name/Description	Part Number
20/30 PRIORITY PACK w/ COPILOT® Bleedback Control Valve	1003327

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: 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