

**DECLARATION OF CONFORMITY**

**Manufacturer:** Abbott Vascular

**Address:** 3200 Lakeside Drive  
Santa Clara, CA 95054

**Manufacturing Sites:** Cashel Road  
Clonmel, Co. Tipperary  
Ireland

**Device Name:** Perclose ProGlide Suture-Mediated Closure System

**Device Classification:** Class IIb

**GMDN Code:** 52747 Femoral artery suture implantation set

**Classification Rationale:** The following Annex IX definition(s) apply to the Perclose ProGlide Suture-Mediated Closure System for purposes of classification: Per Rule 8, Annex IX, all implantable devices and long-term surgically invasive devices are in Class IIb. The Perclose ProGlide Suture-Mediated Closure System is not used in direct contact with the heart or central circulatory system and does not administer medications.

**Authorized European Representative:** Abbott Vascular International BVBA  
Park Lane, Culliganlaan 2B  
1831 Diegem, Belgium

**Model Number:** 12673-05

I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I and Annex II Part 3 of EC Council Directive 93/42/EEC.

Directive 2006/42/EC on Machinery and directive 89/686/EEC on Personal Protective Equipment do not apply.

This declaration is supported by the EC Quality System (Annex II, except Part 4) listed below.



3200 Lakeside Drive  
Santa Clara, CA 95054

Tel: 408-845-3000  
Fax: 408-845-3743

Supporting Certificates:

EC Quality Management System, ISO 13485:2003 Certificate Number: FM 72377  
Annex II Certificate Number: CE 510108

Notified Body: British Standards Institution (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  
Divisional VP, Quality, Compliance, and Analytical Chemistry

Place of issue: Temecula Date of issue: 6/18/15

Effective Date: 6/18/15