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.


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

Version 1.0
June 18, 2015
Supporting Certificates:

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

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