

DECLARATION OF CONFORMITY

Manufacturer: Abbott Vascular

Address: Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA 95054

**Additional
Manufacturing Sites:** Abbott Vascular
Cashel Road
Clonmel
Tipperary
Ireland

Device Name: Perclose ProGlide Suture-Mediated Closure System

Device Classification: Class IIb

GMDN Code: 52747 Femoral vessel suture implantation set

Classification Rationale: The Perclose ProGlide Suture-Mediated Closure System meets the definition in Rule 8 in that the device is an implantable device. It is not intended to be placed in the teeth, does not have a biological effect, is not absorbed and does not undergo chemical change in the body. In addition, the suture is not in direct contact with the central circulatory system according to Definition 1.7. The device does not meet the exceptions listed in Rule 8 and is, therefore, Class IIb.

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

Model Number: 12673-05
12673

I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I and Annex II (except Part 4) 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 an EC quality system certificate listed below.

Supporting Certificates:

EC Quality Management System, ISO 13485:2016

Certificate Number: FM 72377

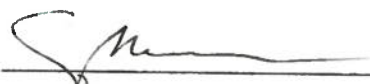
Annex II Certificate Number: CE 510108

Notified Body: BSI Group The Netherlands B.V. (2797)
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands

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.

Authorized Signatory:



13 March 2019

Suzanne Redman, Regulatory Affairs Project Manager

Issued By:



14 Mar 2019

Julie Manalili, Sr. Director Quality, Operations and Compliance

Place of issue:

Temecula, CA

Date of issue:

14 Mar 2019

Effective Date:

27 Feb 2019