Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 95054

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

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.

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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