

DECLARATION OF CONFORMITY

Manufacturer: Abbott Vascular

Address: 3200 Lakeside Drive
Santa Clara, CA 95054

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

Device Name: StarClose SE Vascular Closure System

Device Classification: Class IIb

GMDN Code: 47411 Femoral artery clip closure kit

Classification Rationale: The following Annex IX definition(s) apply to the StarClose SE Vascular Closure System for purposes of classification: Per Rule 8, Annex IX, all implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended: to be used in direct contact with the heart, the central circulatory system, or the central nervous system, in which case they are in Class III

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

Model Number: 14679-02

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 1989/686/EC on Personal Protective Equipment do not apply.



3200 Lakeside Drive
Santa Clara, CA 95054

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

This declaration is supported by an EC Quality System and design examination approval (Annex II Part 3) listed below.

Supporting Certificates:

EC Quality Management System, ISO 13485:2003 Certificate Number: FM72377
Annex II Certificate Number: CE510108

Notified Body: British Standards Institution
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 and EC Design Examination certificates 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: 4/3/15

Effective Date: 4/3/15