

DECLARATION OF CONFORMITY

Manufacturer: Abbott Vascular

Address: 3200 Lakeside Drive
Santa Clara, CA 95054

Manufacturing Sites: Cashel Road
Clonmel, Co. Tipperary
Ireland

Device Name: Prostar XL Percutaneous Vascular Surgical System

Device Classification: Class IIb

GMDN Code: 52747 Femoral artery suture implantation set

Classification Rationale: The following Annex IX definition(s) apply to the Prostar XL Percutaneous Vascular Surgical System for purposes of classification: Per Rule 8, Annex IX, all implantable devices and long-term surgically invasive devices are in Class IIb. The Prostar XL Percutaneous Vascular Surgical 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: 12322-02

I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I and Annex II (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 the EC Quality System Annex II listed below.

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: David L. Cato for Susan Slane

Susan Slane

Divisional VP, Quality, Compliance, and Analytical Chemistry

Place of issue: TEMECULA, CA Date of issue: NOV 3, 2015

Effective Date: NOV 3, 2015

This memo delegates my signature authority to: Scope of delegation authority includes: Delegation begins on: Delegation ends on: Name: Title: Signature: Date: **Attach this evidence of delegation to all records being approved.**

CONFIDENTIAL-

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