## **DECLARATION OF CONFORMITY**

Manufacturer:

Evalve, Inc.

Address:

4045 Campbell Ave.

Menlo Park, CA 94025

Manufacturing Site:

3885 Bohannon Drive, Menlo Park, CA 94025

Device Name:

Lift, Support Plate, and Stabilizer

Device Classification:

Class I, Non-sterile

GMDN Code / Term:

60466 / Vascular graft implantation tool base

Classification Rationale:

Rule 1 of Annex IX: all non-invasive devices are in Class I, if no

other rule applies.

Authorized European

Abbott Vascular International BVBA

Representative:

Park Lane, Culliganlaan 2B

1831 Diegem, Belgium

## Model Numbers:

Product Information		Effective Date	
Description	Catalogue Number	Start	Stop
Lift	LFT01ST	5/27/2008	N/A
Support Plate	PLT01ST	5/27/2008	N/A
Stabilizer	SZR01ST	5/27/2008	N/A

I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I of EC Council Directive 93/42/EEC.

This declaration is made in accordance with Annex VII 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.

## **Supporting Certificates:**

EC Quality Management System, EN ISO13485:2003, Certificate Number: FM 630291

## **Notified Body:**

BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP United Kingdom Notified Body Identification Number: 0086

DOC#	Rev.	Rev. Date	Page
DOC-003	Z	2015-Арг-23	Page 1 of 2

This Declaration of Conformity expires upon revision or with the revision or expiration of any of

Effective Date: April 33, 2015

 DOC#
 Rev.
 Rev. Date
 Page

 DOC-003
 Z
 2015-Apr-23
 Page 2 of 2