DECLARATION OF CONFORMITY

Manufacturer:	Evalve, Inc. (DBA Abbott Vascular Inc.)
Address:	4045 Campbell Avenue Menlo Park, CA 94025
Manufacturing Site:	3885 Bohannon Drive, Menlo Park, CA 94025
Device Name:	**Steerable Guide Catheter**
Device Classification:	Class III
GMDN Code / Term:	56280 / Mitral Valve Repair System
Classification Rationale:	Rule 7 of Annex IX: all surgically invasive devices intended for short-term use to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body are in Class III.
Authorized European Representative:	Abbott Vascular International BVBA Park Lane, Culliganlaan 2B 1831 Diegem, Belgium

Model Numbers:

Product Information	
Description	**Catalogue Number**
Steerable Guide Catheter (SGC)	SGC01ST

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

This declaration is supported by an EC quality system (Annex II) and design examination approval listed below.

Supporting Certificates:

Quality Management System, ISO 13485:2003: Certificate Number: FM 630291
EC Quality Assurance System Certificate: CE 630565
EC Design Examination Certificate Number: CE 630566

Notified Body:

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

This Declaration of Conformity is issued under the sole responsibility of the manufacturer and expires upon revision or with the revision or expiration of any of the supporting certificates listed above.

By: _____ Date: 3/20/15

Susan Slane
Divisional VP, AV Global Quality and Compliance
Abbott Vascular

By: _____ Date: March 20, 2015

Michelle Grossman
Director Regulatory Affairs
Abbott Vascular

Place of Issue: Santa Clara, CA Date of Issue: March 20, 2015

Effective Date: March 20, 2015