# DECLARATION OF CONFORMITY

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|---|---|
| Manufacturer: | Evalve, Inc. (DBA Abbott Vascular Inc.) |
| Address: | 4045 Campbell Avenue<br>Menlo Park, CA 94025 |
| Manufacturing Site: | 3885 Bohannon Drive, Menlo Park, CA 94025 |
| Device Name: | **MitraClip Delivery System** |
| Device Classification: | Class III |
| GMDN Code / Term: | 56280 / Mitral valve tissue repair system |
| Classification Rationale: | Rule 8 of Annex IX: all surgically invasive devices to be used in direct contact with the heart, the central circulatory system or the central nervous system are in Class III. |
| Authorized European Representative: | Abbott Vascular International BVBA<br>Park Lane, Culliganlaan 2B<br>1831 Diegem, Belgium |

Model Numbers:

| Product Information | |
|---|---|
| **Description** | **Catalogue Number** |
| MitraClip Delivery System (CDS) | CDS02ST |

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:**

EC Quality Management System, ISO 13485:2003, Certificate Number: FM 630291
EC Quality Assurance System Certificate Number: 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