

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Establishment Labs S.A.  
Coyol Free Zone & Business Park Building  
4th Street, Building B15  
Alajuela  
Costa Rica

DUNS Number: 85-316-6098

Holds Certificate No:

**MDSAP 664713**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2003 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D, 21 CFR 821

Design, production and distribution of silicone components and silicone implantable medical devices.

For and on behalf of BSI:

  
\_\_\_\_\_  
Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2017-06-14

Effective Date: 2017-06-14

Expiry Date: 2019-02-28



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 664713**

Location

Establishment Labs S.A.  
Coyol Free Zone & Business Park Building  
4th Street, Building B15  
Alajuela  
Costa Rica  
DUNS Number: 85-316-6098

Registered Activities

Design, production and distribution of silicone components and silicone implantable medical devices.

Establishment Labs SA  
Coyol Free Zone & Business Park Building  
4th Street, Building B-25  
Alajuela  
Costa Rica

Design, production and distribution of silicone components and silicone implantable medical devices.



Original Registration Date: 2017-06-14

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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.