

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

Reglera LLC
555 Zang Street
Lakewood
Colorado
80228
USA

Holds Certificate No: **FS 524102**

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

Provider of quality and regulatory outsourcing services and service products for the biomedical industry.

These include but are not limited to medical device, in vitro diagnostics, and tissue markets.

The activities to be covered in this registration are:

Document Change Control System (service product) Training Record Management (service product) Complaint Handling and Adverse Event Reporting (service product) Supplier and Internal Audit Program (service product), Donor Eligibility Outsourcing (service product) as well as consulting services.

For and on behalf of BSI:



President, BSI Management Systems America, Inc.

Originally Registered: **01/03/2008**

Latest Issue: **01/28/2009**

Expiry Date: **01/02/2011**



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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](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.