

# Certificate of Approval

This is to certify that the Management System of:

## Scantibodies Laboratory, Inc.

9336 Abraham Way, Santee, CA, 92071, United States

has been approved by LRQA to the following standards:

ISO 13485:2003



Chris Koci

Issued By: Lloyd's Register Quality Assurance, Inc. for and on behalf of: Lloyd's Register Quality Assurance Ltd

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current Issue Date: 1 September 2017

Expiry Date: 1 March 2019

Certificate Identity Number: 10028404

Original Approvals:

ISO 13485 15 August 1996

Approval Certificate Number: ISO 13485 – 00006249

The scope of this approval is applicable to:

Design, Development, Manufacture, and Distribution of Serum, Controls, Antibodies, In Vitro Diagnostic Reagents and Kits. Collection and Distribution of Human Source Plasma, Specialty Plasma, and Blood Products for Therapeutic, Research, and In Vitro Diagnostics.



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# Certificate Schedule

Certificate Identity Number: 10028404

Location	Activities
9336 Abraham Way, Santee, CA, 92071, United States	ISO 13485:2003 Design, Development, Manufacture, and Distribution of Serum, Controls, Antibodies, In Vitro Diagnostic Reagents and Kits.
Laboratorios Scantibodies, S.A. de C.V. Calle Los Vinedos #4100, Parque Industrial El Bajio, 21430 Tecate, Mexico	ISO 13485:2003 Development, Manufacture and Distribution.
Laboratories Scantibodies, S.A. de C.V. Calle del Bajio #5000, Parque Industrial El Bajio, 21430 Tecate, Mexico	ISO 13485:2003 Development, Manufacture and Distribution.
Scantibodies Biologics Incorporated 1068 Broadway, El Cajon, CA, 92021, United States	ISO 13485:2003 Collection and Distribution of Human Source Plasma, Specialty Plasma, and Blood Products for Therapeutic, Research, and In-Vitro Diagnostic Use.
10946 Woodside Avenue North, Santee, CA, 92071, United States	ISO 13485:2003 Development and Manufacture.
2365 San Vicente Road (Ranch), Ramona, CA, 92065, United States	ISO 13485:2003 Development and Manufacture.
9216 Abraham Way, Santee, CA, 92071, United States	ISO 13485:2003 Development and Manufacture.
9236 Abraham Way, Santee, CA, 92071, United States	ISO 13485:2003 Development and Manufacture.



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# Certificate Schedule

Certificate Identity Number: 10028404

Location	Activities
9343 Wheatlands Road, Santee, CA, 92071, United States	ISO 13485:2003 Distribution.
2311 Marconi Court, San Diego, CA, 92154, United States	ISO 13485:2003 Distribution.



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