

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 13485:2016



Chris Koci - President, LRQA Americas

Issued By: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

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: 11 June 2018

Expiry Date: 31 August 2020

Certificate Issue Number: 10092343

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 Issue Number: 10092343

Location	Activities
9336 Abraham Way, Santee, CA, 92071, United States	ISO 13485:2016 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 13485:2016 Development, Manufacture and Distribution.
Laboratorios Scantibodies, S.A. de C.V. Calle del Bajio #5000, Parque Industrial El Bajio, 21430 Tecate, Mexico	ISO 13485:2016 Development, Manufacture and Distribution.
Scantibodies Biologics Incorporated 1068 Broadway, El Cajon, CA, 92021, United States	ISO 13485:2016 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 13485:2016 Development and Manufacture.
2365 San Vicente Road (Ranch), Ramona, CA, 92065, United States	ISO 13485:2016 Development and Manufacture.
9216 Abraham Way, Santee, CA, 92071, United States	ISO 13485:2016 Development and Manufacture.
9236 Abraham Way, Santee, CA, 92071, United States	ISO 13485:2016 Development and Manufacture.
9343 Wheatlands Road, Santee, CA, 92071, United States	ISO 13485:2016 Distribution.



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Location	Activities
2311 Marconi Court, San Diego, CA, 92154, United States	ISO 13485:2016 Distribution.



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