Certificate US20/819944041

The management system of



Scantibodies Laboratories, Inc.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Manufacturing and distribution of serum, controls, antibodies, in vitro diagnostic reagents and kits. Manufacturing of blood products for research and in vitro diagnostics.

This certificate is valid from 27 August 2023 until 27 August 2026 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 27 August 2020

Certified activities performed by additional sites are listed on subsequent pages.

Jordhan M. Hall

Authorised by Jonathan Hall Global Head - Certification Services

SGS United Kingdom Ltd Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK t +44 (0)151 350-6666 - www.sgs.com





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Scantibodies Laboratories, Inc.

ISO 13485:2016

EN ISO 13485:2016	

Issue 6 Sites

Scantibodies Laboratories. Inc.

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

Manufacturing of products in the scope of certification.

Scantibodies Laboratory, Inc.

9236 Abraham Way, Santee, CA, 92071, United States Of America

Manufacturing of products in the scope of certification.

Scantibodies Laboratory, Inc.

9216 Abraham Way, Santee, CA, 92071, United States Of America

Manufacturing of products in the scope of certification.

Scantibodies Laboratories, Inc.

9343 Wheatlands Rd, Santee, CA, 92071, United States Of America

Warehouse and Distribution of products in the scope of certification.

Scantibodies Laboratories. Inc.

10946 N. Woodside Ave., Santee, CA, 92071, United States Of America

Purchasing, Quality Management System support and Human resources in support of Manufacture and distribution of products in the scope of certification.





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Certificate US20/819944041, continued



Scantibodies Laboratories, Inc.

ISO 13485:2016 EN ISO 13485:2016

Scantibodies Laboratories. Inc.

2365 San Vicente Road, Ramona, CA, 92065, United States Of America

Manufacture of antibodies

Scantibodies Laboratories, Inc.

2311 Marconi Court, San Diego, CA, 92154, United States Of America

Warehouse and distribution of products in the scope of certification.

Scantibodies Laboratories, Inc.

1658 Gailes Blvd, , San Diego , CA, 92154, United States Of America

Warehouse and distribution of products in the scope of certification.

Scantibodies Laboratories, Inc.

Calle Los Viñedos No. 4100, Parque Industrial El Bajio (Building A), Tecate, Baja California, 21430, Mexico

Manufacture of products in the scope of certification.

Purchasing, Quality Management System support and Human resources in support of Manufacture and distribution of products in the scope of certification.

Laboratorios Scantibodies, S.A. de C.V.

Calle Del Bajio No.5000, Parque Industrial El Bajio (Building B), Tecate, Baja California, 21430, Mexico

Manufacturing, Packaging, Warehouse and Distribution of products in the scope of certification.





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