

Certificate US20/819944041



The management system of

Scantibodies Laboratories, Inc.

9336 Abraham Way
Santee, CA 92071, United States

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 therapeutic, research and in vitro diagnostics. Contract manufacturing of serum, controls, antibodies, in vitro diagnostic reagents and kits.

This certificate is valid from 3 August 2021 until 27 August 2023 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 2. Certified since 27 August 2020.

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

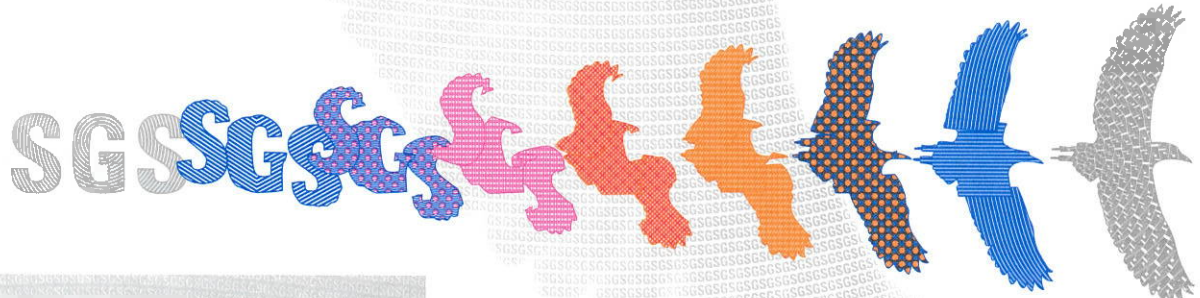
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Scantibodies Laboratories, Inc.

ISO 13485:2016 EN ISO 13485:2016



Issue 2

Detailed scope (applicable to all sites):

Manufacturing and distribution of serum, controls, antibodies, in vitro diagnostic reagents and kits.

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

Additional facilities:

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

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

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

9216 Abraham Way, Santee, CA 92071, United States

9236 Abraham Way, Santee, CA 92071, United States

1658 Gales Blvd, , San Diego, CA 92154, United States

9343 Wheatlands Rd, Santee, CA 92071, United States

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

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



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