




America

CERTIFICATE

No. QS6 105803 0001 Rev. 00

Certificate Holder: **Biolegend Inc.**
8999 Biolegend Way, GMP Suite
San Diego CA 92121
USA

Certification Mark:



Scope of Certificate: **Design, Development, Manufacturing and Distribution of In-Vitro Diagnostic Reagents and Test Kits for the Following Applications: Immunological Typing and Testing, Neurological Typing and Testing**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **11-924-0658**

Effective Date: **2020-06-15**

Expiry Date: **2023-06-14**

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Date of Issue: 2020-08-18

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services



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Regulatory Requirements: Audit/Certification Criteria

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Biolegend Inc.
8999 Biolegend Way, GMP Suite, San Diego CA 92121,
USA

Biolegend, Inc.
8991 Biolegend Way, San Diego CA 92121, USA

Biolegend Inc.
8988 Biolegend Way, San Diego CA 92121, USA

BioLegend, Inc.
8999 Biolegend Way, San Diego CA 92121, USA

Facility Scopes:

Biolegend Inc.
8999 Biolegend Way, GMP Suite, San Diego CA 92121,
USA

Design, Development, Manufacturing and Distribution
of In-Vitro Diagnostic Reagents and Test Kits for the
following Applications: Immunological Typing and
Testing, Neurological Typing and Testing
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Biolegend Inc.
8991 Biolegend Way, San Diego CA 92121, USA

Quality Assurance and Regulatory Affairs
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Biolegend Inc.

8988 Biolegend Way, San Diego CA 92121, USA

Executive Management, Human Resources, Planning
and Procurement, Customer and Technical Services
DUNS No: 11-924-0658

BioLegend, Inc.

8999 Biolegend Way, San Diego CA 92121, USA

Design and Development, Receiving Inspection,
Manufacturing, Quality Control, Quality Assurance,
Facilities Management, Warehousing and Distribution
DUNS No: 11-924-0658

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