

Certificate



Certificate No.: MD 741172 145619-20

Manufacturer: **One Lambda, Inc.**
21001 Kittridge Street
Canoga Park, CA 91303
USA

D-U-N-S No.: 11-828-9289

Certification criteria: ISO 13485:2003

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure

Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC
ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD
Act (as applicable)

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and Development, Manufacture, Distribution, Servicing and
Installation of in Vitro Diagnostics assays reagents, instruments and
software for determination of tissue groups used in the field of
compatibility testing for transplantation diagnostics.

TUV Rheinland of North America, Inc., an MDSAP authorized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 145619-20
Issue Date: 2017-10-10
Effective Date: 2017-10-10
Expiry Date: 2020-05-09



A handwritten signature in blue ink, appearing to read "H. Lüdemann", written over a horizontal line.

Certification officer: Dr. H. Lüdemann
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.

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Manufacturer: **One Lambda, Inc.**
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Canoga Park, CA 91303
USA

Scope: The scope of Certification also includes the following additional sites:

One Lambda, Inc.
21200 Oxnard Street
Woodland Hills, CA 91367
USA
D-U-N-S No.: 11-828-9289

Scope: Warehousing, Incoming receipt inspection, and Distribution;
software Development for Medical Devices in the field of HLA Tissue
Typing

One Lambda, Inc.
6709 Independence Avenue
Canoga Park, CA 91303
USA
D-U-N-S No.: 11-828-9289

Scope: Design and Development of In Vitro Diagnostic Assays

Project No.: 145619-20
Issue Date: 2017-10-10
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