

Certificate

Certificate No.: MD 2233216-1-2

Manufacturer: **One Lambda, Inc.**
22801 Roscoe Blvd.
West Hills CA 91304
USA

REPs Facility ID: F003909

Certification criteria: ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure
Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
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 HLA tissue groups used in compatibility
testing for transplantation diagnostics.

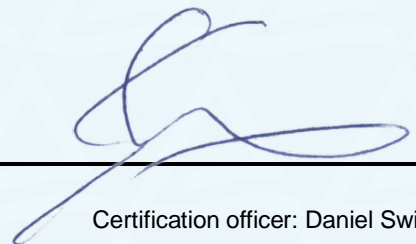
TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject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

Project No.: 234228067-11

Issue Date: 2025-05-23

Effective Date: 2025-06-10

Expiry Date: 2028-06-09


Certification officer: Daniel Swiatko
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.

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The scope of certification also covers the following sites:

No.	Location	Scope
/01	One Lambda, Inc. A Thermo Fisher Scientific Brand 22801 Roscoe Blvd. West Hills CA 91304 USA	REPS Facility ID: F003909 Activities related to Design and Development, Manufacture, Distribution, Servicing and Installation.
/02	One Lambda, Inc. Neuendorfstr. 25 16761 Hennigsdorf Germany	REPS Facility ID: N/A Activities related to the customer service and complaint investigation.


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