Certificate

Certificate No.: MD 2233216-1

Manufacturer: **One Lambda, Inc.**

22801 Roscoe Blvd.
West Hills CA 91304
USA

Digitally signed by Ceaicovschi Tudor
Date: 2023.09.22 15:58:40 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

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 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.: 234186395-12

Issue Date: 2022-07-28

Effective Date: 2022-07-28

Expiry Date: 2025-06-09

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Aihe Huang
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000010776?locale=en or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

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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, Service 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.

Project No.: 234186395-12

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