Certificate

TÜVRheinland®

Certificate No.:	MD 2233216 234120969-10
Manufacturer:	**One Lambda, Inc.** 22801 Roscoe Blvd West Hills, CA 91304 USA
D-U-N-S No.:	11-828-9289
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. 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 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.:	31895531.002
Issue Date:	2020-05-20
Effective Date:	2020-05-20
Expiry Date:	2023-05-26

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Songni

Certification officer: S. Liu
TUV Rheinland of North America, Inc.

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

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

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