

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2233216-1
Certificate Holder: One Lambda, Inc.
A Thermo Fisher Scientific Brand
22801 Roscoe Blvd.
West Hills CA 91304
USA

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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 234228067-11
Effective date: 2025-06-10
Expiry date: 2028-06-09
Issue date: 2025-05-23
Replaces certificate SX 2233216-1 issued 2022-07-28

This certificate can be validated on <https://www.certipedia.com>


Daniel Swiatko
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Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	One Lambda, Inc. 22801 Roscoe Blvd. West Hills CA 91304 USA	Activities related to Design and Development, Manufacture, Distribution, Installation and Service.
/02	One Lambda, Inc. Neuendorfstr. 25 16761 Hennigsdorf Germany	Activities related to the customer service and complaint investigation.

This certificate can be validated on <https://www.certipedia.com>