

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2233216-1

Organization: One Lambda, Inc.
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 tissue groups used in the field of 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.: 234186395-11
Effective date: 2022-07-28
Expiry date: 2025-06-09
Issue date: 2022-07-28



Aihe Huang
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TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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EN ISO 13485:2016**

Registration No.: SX 2233216

Organization: One Lambda, Inc.
A Thermo Fisher Scientific Brand
22801 Roscoe Blvd.
West Hills CA 91304
USA

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.

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