

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

One Lambda, Inc.
21001 Kittridge Street
Canoga Park CA 91303
USA

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope and additional site(s) included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-01-14
Certificate Registration No.: SX 60135773 0001
An audit was performed. Report No.: 31892060 001
This Certificate is valid until: 2022-01-13



D-ZM-14169-D1-02

Date 2019-01-14



TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90424 Nürnberg



TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60135773 0001
Report No.: 31892060 001

Organization: One Lambda, Inc.
21001 Kittridge Street
Canoga Park CA 91303
USA

Scope:

Additional Sites:

One Lambda, Inc.
22801 Roscoe Blvd., West Hills, CA 91304, USA
Scope: Activities associated with Warehousing, Incoming
Receipt Inspection, and Distribution; Software Development
for Medical Devices in the field of HLA Tissue Typing

One Lambda, Inc.
6709 Independence Avenue, Canoga Park, CA 91303
Scope: Activities associated with Design and Development of
in vitro diagnostic assays

One Lambda GmbH
Neuendorsfstr.25, 16761 Henningsdorf Germany
Scope: Activities related to customer service and
complaint investigation



Certification Body



Date: 2019-01-14

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60135773 0001
Report No.: 31892060 001

Organization: One Lambda, Inc.
21001 Kittridge Street
Canoga Park CA 91303
USA

Scope:

Design and Development, Manufacturing, Distribution,
Servicing and Installation of in vitro diagnostic assays,
reagents, instruments and software for determination of
tissue groups used in the field for compatibility
testing for transplantation diagnostics

