

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
One Lambda, Inc.
22801 Roscoe Blvd
West Hills CA 91304
USA

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

(see attachment for scope and additional site 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: 2020-07-07
Certificate Registration No.: SX 60143059 0001
An audit was performed. Report No.: 31895531 001
This Certificate is valid until: 2022-07-11

Certification Body



Date 2020-07-07



Song Li

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60143059 0001
Report No.: 31895531 001

Organization: One Lambda, Inc.
22801 Roscoe Blvd
West Hills CA 91304
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

Certification Body



Date: 2020-07-07

S. Liu
S. Liu

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60143059 0001
Report No.: 31895531 001

Organization: One Lambda, Inc.
22801 Roscoe Blvd
West Hills CA 91304
USA

Scope: Additional Site:

One Lambda GmbH
Neuendorfstr. 25
16761 Henningsdorf
Germany

Scope: Activities related to customer service and
complaint investigation

Certification Body



Date: 2020-07-07

S. Liu
S. Liu