

# Certificate



TUV Rheinland of North America, Inc., a CMDCAS  
recognized registrar, certifies that

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

has established and maintained a

**Quality Management System  
according to  
ISO 13485:2003**

Audit Report No.:	31593665 001
Certificate Registration No.:	74 500 4891
Expiry Date:	June 03, 2019

for the 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

(see attachment for additional site(s) included)



Certification Officer: Dr. H. Lüdemann

TUV Rheinland of North America, Inc.  
Newtown, Connecticut

Effective Date: June 04, 2016

Attachment  
**Quality Management System  
according to ISO 13485:2003**

for

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

The scope of the registration includes the following sites:

**One Lambda, Inc.**

21200 Oxnard Street, Woodland Hills, CA 91367, US

**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 assay

**One Lambda GmbH**

Neuendorsfstr.25, 16761 Henningsdorf Germany

**Scope:** Activities related to customer service and complaint investigation

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Certification Officer: Dr. Heiner Luedemann

TUV Rheinland of North America, Inc.  
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