

EC Certificate
Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60111158 0001

Report No.: 31593665 001

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

Products: In vitro diagnostic assays and reagents for the determination of HLA tissue groups
Products: see attachment
Replaces Approval, Registration No.: HL 60039388 0001

Expiry Date: 2021-06-03

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2016-06-04

Date: 2016-06-02



Notified Body


Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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Products:

HLA Class I and Class Antigen Typing Products

- AllSet Gold+ SSP
- SeCore Sequence Based Typing
- Micro SSP DNA Typing Tests
- LABType
- HLA Tissue Typing Tests

HLA Antibody Screening

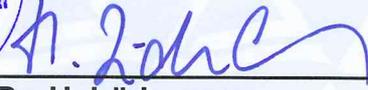
- ClqScreen
- FlowPRA Screening Tests
- LABScreenMulti
- LABScreen
- Lambda Cell Trays
- Lambda Antigen Trays

Monoclonal Antibodies for cell surface antigens

- Fluorescent Conjugated Monclonal Antibodies



Notified Body


Dr. H. Lüdemann

Date: 2016-06-04