

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate

Registration No.: HL 60111158 0002

Report No.: 31890461 001

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

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
- AllType NGS 11-Loci Amplification Kit

HLA Antibody Screening

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

Monoclonal Antibodies for cell surface antigens

- Fluorescent Conjugated Monoclonal Antibodies

Date: 2018-05-04


Dipl.-Ing. Sven Hoffmann



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 0002

Report No.: 31890461 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 60111158 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: 2018-05-04

Date: 2018-05-04



Dipl.-Ing. Sven Horn

TÜV Rheinland LGA Products GmbH- Tillystraße 2-90431 Nurnberg

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.