

EC Certificate

Full Quality Assurance System Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV excluding (4, 6)

Registration No.:

HL 2233216-1

Manufacturer:

One Lambda, Inc.

A Thermo Fisher Scientific Brand

22801 Roscoe Blvd. West Hills CA 91304

USA

Products:

HLA Class I and Class II 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

- LinkSeq HLA Typing Kits

AllType FASTplex NGS Flex HLA Typing
 AllType FASTplex NGS HLA Typing

HLA Antibody Screening

- C1qScreen

- FlowPRA Screening Tests

LABScreenMulti

- LABScreen

- Lambda Cell Trays

- Lambda Antigen Trays

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.

Report No.:

234172533-40

Effective date:

2020-07-08

Expiry date:

2025-05-26

Issue date:

2022-02-09

Katja Mierisch

TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

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.

Page 1 of 2



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One Lambda, Inc.

A Thermo Fisher Scientific Brand

22801 Roscoe Blvd. West Hills CA 91304

USA

Products:

Monoclonal Antibodies for cell surface antigens

- Fluorecent Conjugated Monclonal Antibodies

Replaces Approval, Registration No.: HL 60143129 0001

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Page 2 of 2

One Lambda, Inc. 22801 Roscoe Blvd. West Hills, CA 91304 Tel 747.494.1000 Fax 747,494,1001 www.onelambda.com

CERTIFICATE FOR A EC DIRECTIVE 98/79/EC ANNEX IV, ARTICLE 3

As the responsible official for One lambda, Inc., a part of Thermo Fisher Scientific, I hereby certify that One Lambda, Inc. has been approved for EC Directive 98/79/EC Annex IV, Article 3 and holds a Certificate issued by TUV Rhineland Product Safety GmbH. In addition, One Lambda, Inc. complies with all applicable and pertinent international regulations associated with this certificate and conforms to current Good Manufacturing Practices (cGMP) and FDA regulations. A photocopy of the Certificate for EC Directive 98/79/EC Annex IV Article 3 may be used as long as this original statement is attached.

hn Nelson	
gulatory Affairs Specialist II	
CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT	CIVIL CODE § 1189
A notary public or other officer completing this certificate verifies only to which this certificate is attached, and not the truthfulness, accurac	
	,, or family or distribution
State of California Angeles) County of Los Angeles)	avni Kovdzhyan Notzry Po

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his or her authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or entity upon behalf of which the person(s) acted, executed the instrument.

AGAVNI KOVDZHYAN Notary Public - California Los Angeles County Commission # 2414433 My Comm. Expires Sep 1, 2026

Place Notary Seal Above

I certify under PENALITY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Lanni Kovazyca