EC Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Katja Mierisch
TÜV Rheinland LGA Products GmbH
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Digitally signed by Ceaicovschi Tudor
Date: 2023.08.10 11:28:07 EEST
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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.

EC Certificate

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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: Monoclonal Antibodies for cell surface antigens
- Fluorecent Conjugated Monclonal Antibodies

Replaces Approval, Registration No.: HL 60143129 0001

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