



APPROVAL
EC Directive 98/79/EC Annex IV, Article 3
Full Quality Assurance System
In vitro diagnostic medical devices

Registration No.: HL 60014234 0001

Report No.: 30592735 001

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

Scope: Design, manufacturing and distribution of in vitro diagnostic assays and reagents for the determination of HLA tissue groups

Products: see attachment

Replaces Approval, Registration No.: HL 60006566 0001

Date of Expiry: 25.06.2011

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex IV, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex IV, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 26.06.2006



Notified Body

H. Lüdemann
Dr. H. Lüdemann

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE



Doc. 1/1, Rev. 0

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: HL 60014234 0001
Report No.: 30592735 001

Manufacturer: One Lambda, Inc.
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Scope: HLA - class I and II Antigen Typing Products:

- HLA Tissue Typing Trays
- Micro SSP Products
- LABType - SSO DNA Typing Test
- HLA-B27 FITC Conjugated Monoclonal Antibody

HLA-Antibody Screening Products:

- Lambda Cell Trays
- Lambda Antigen Trays
- Flow PRA Screening Test
- LABScreen

Cologne, 26.06.2006




Dr. H. Lüdemann