

APPROVAL

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

Registration No.: HL 60023480 0001

Report No.: 30890039 001

Manufacturer: Tepnel Lifecodes
Molecular Diagnostics
550 West Avenue
Stamford, CT 06902
USA

Scope: Design/Development and Manufacture of
in vitro Diagnostic HLA Typing Kits

Products: see attachment

Replaces Approval, Registration No.: HL 60008450 0001


Date of Expiry: 01.12.2013

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, 02.12.2008



Notified Body


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

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

Doc. 1/1, Rev. 0

Attachment to
Registration No.: HL 60023480 0001
Report No.: 30890039 001

Manufacturer: Tepnel Lifecodes
Molecular Diagnostics
550 West Avenue
Stamford, CT 06902
USA

Scope: LIFECODES HLA SSO Typing Kits:

- LIFECODES HLA A Typing Kit
- LIFECODES HLA B Typing Kit
- LIFECODES HLA DRB Typing Kit
- LIFECODES HLA DRB1 Typing Kit

Cologne, 02.12.2008



Certification Body



Dr. H. Lüdemann