

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

Registration No.: HL 60021353 0001

Report No.: 21135130 003

Manufacturer: Immunolab GmbH
Otto-Hahn-Str. 16
34123 Kassel
Deutschland

Scope: Design/Development and Production of in vitro immune diagnostic test kits for the determination of antibodies against infectious agents

Products: see attachment

Date of Expiry: 07.05.2013

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, 08.05.2008



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

Attachment to
Registration No.: HL 60021353 0001
Report No.: 21135130 003

Manufacturer: Immunolab GmbH
Otto-Hahn-Str. 16
34123 Kassel
Deutschland

Scope: Products:

- Anti-CMV-ELISA (IgG, IgM)
- Anti-Toxoplasmosis-ELISA (IgG, IgM)
- Anti-Rubella-ELISA (IgG, IgM)

Cologne, 08.05.2008




Dr. H. Lüdemann