



TÜVRheinland®

## APPROVAL

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

Registration No.: HL 60025008 0001

Report No.: 21139314 001

**Manufacturer:** Minerva Biolabs GmbH  
Landhausring 7  
12683 Berlin  
Deutschland

**Scope:** Design, development and production of molecular  
in vitro diagnostic products for the detection  
of infectious diseases

Products: see attachment

**Date of Expiry:** 18.03.2014

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, 20.10.2009



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.



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

Attachment to  
Registration No.: HL 60025008 0001  
Report No.: 21139314 001


Manufacturer: **Minerva Biolabs GmbH**  
**Landhausring 7**  
**12683 Berlin**  
**Deutschland**

Scope: Product:  
Onar<sup>®</sup> Ct - Chlamydia trachomatis  
Detection Kit for qPCR

Cologne, 20.10.2009



Certification Body

  
Dr. H. Lüdemann