

Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization
R.O.S.E. Europe GmbH
Industriepark Höchst
65929 Frankfurt
Deutschland

has established and applies a quality management system
for the following scope:

**Design and Development, Production and Sales of
HLA Typing Kits**

Proof has been furnished that the requirements specified in

EN ISO 9001:2000

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SY 60018633 0001

An audit was performed. Report No.: 21128082 004

This Certificate is valid until: 02.07.2012

Cologne, 10.07.2007



Certification Body


Dr. H. Lüdemann

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

Tel.: (+49/221) 806 - 1371 Fax: (+49/221) 806 - 3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization
R.O.S.E. Europe GmbH
Industriepark Höchst
65929 Frankfurt
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Production and Sales of
HLA Typing Kits**

Proof has been furnished that the requirements specified in

EN ISO 13485:2003

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60018632 0001

An audit was performed. Report No.: 21128082 004

This Certificate is valid until: 02.07.2012



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

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

Attachment to
Registration No.: HL 60018631 0001
Report No.: 21128082 004

Manufacturer: R.O.S.E. Europe GmbH
Industriepark Höchst
65929 Frankfurt
Deutschland

Scope: **Products:**
HLA Typing Kits
- HLA-A*23:01 SSP Typing Kits

Cologne, 10.07.2007




Dr. H. Lüdemann

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

Registration No.: HL 60018631 0001

Report No.: 21128082 004

Manufacturer: R.O.S.E. Europe GmbH
Industriepark Höchst
65929 Frankfurt
Deutschland

Scope: Design and Development, Production and Sales of
HLA Typing Kits

Products: see attachment

Date of Expiry: 02.07.2012

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, 10.07.2007



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