

**EC Certificate**  
**Directive 98/79/EC Annex IV, excluding Sections 4 and 6**  
**Full Quality Assurance System**  
**In Vitro Diagnostic Medical Devices**

**Registration No.:** HL 60077541 0001

**Report No.:** 21183895 001

**Manufacturer:** R.O.S.E. Europe GmbH  
Daimler Str. 6  
61449 Steinbach  
Deutschland

**Products:** HLA Typing Kits  
  
(see attachment for products and sites included)  
  
Replaces Certificate, Registration No.: HL 60018631 0001

**Expiry Date:** 2017-07-24

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

**Effective Date:** 2012-07-25

**Date:** 2012-07-25



Notified Body

  
Dr. H. Lüdemann

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HL 60077541 0001

**Report No.:** 21183895 001

**Manufacturer:** R.O.S.E. Europe GmbH  
Daimler Str. 6  
61449 Steinbach  
Deutschland

**Products included:**

**HLA Typing Kits**

- HLA-ABDR SSP Typing Kits
- HLA-ABDR SBT Typing Kits

**Site included:**

Beijing ROSE Co-Win Medical Tech., Co. Ltd.  
Changqing Science Park  
Xing Huo Road 6  
CHANGPING District  
102200 Beijing, P.R.China

**Acitivities related to production of HLA Typing Kits**

**Date:** 2012-07-25



**Notified Body**

  
**Dr. H. Lüdemann**