

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
R.O.S.E. Europe GmbH
Daimler Str. 6
61449 Steinbach
Deutschland

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

**Design and development, production and distribution of
HLA Typing Kits
(see attachment for additional sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2003 + AC:2009

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

Certificate Registration No.: SX 60077543 0001

An audit was performed. Report No.: 21183895 001

This Certificate is valid until: 24.07.2017



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



Certification Body

Date 25.07.2012


Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60077543 0001
Report No.: 21183895 001

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

Scope: 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



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Dr. H. Lüdemann

Date: 2012-07-25