



# Certificate

The Certification Body of  
TÜV Rheinland Product Safety GmbH



hereby certifies that the organization

**SUZHOU KANGLI  
ORTHOPAEDICS INSTRUMENT CO., LTD.**  
Jinfeng Town of Zhang Jia Gang  
Suzhou City

**Jiangsu, 215625  
China**

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

**Design, Manufacturing and Sales of non-sterile Orthopedic  
Internal Fixation Devices and Instrumentation for use  
in association with Orthopedic Internal Fixation Devices**

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 60016559 0001

An audit was performed. Report No.: 16700702 001

This Certificate is valid until: 23.01.2012



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

Cologne, 24.01.2007

Certification Body



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

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TÜV Rheinland Product Safety GmbH D-51105 Cologne

SUZHOU KANGLI  
ORTHOPAEDICS INSTRUMENT CO., LTD.  
Jinfeng Town of Zhang Jia Gang  
Ms. Lu  
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Customer Service Center for  
Product Safety and Quality  
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Cologne, 24 January 2007

复印件

Application for : QMS  
Certificate No. : SX 60016559 SHEET 0001  
Techn. appliance : Only for QM-System audit  
Test requirements : EN ISO 13485:2003

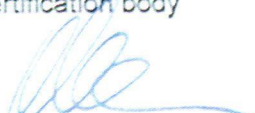
Dear Ms. Lu,

Your Quality Management System has been tested and found to be in  
accordance with the above mentioned requirements.

Enclosed please find the certificate  
No. SX 60016559 0001.

Kind regards

Certification body



Dipl.-Ing. D. Meier

Test sample: no, documentation available

TÜV Rheinland  
Product Safety GmbH

TÜV Rheinland Group

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51105 Cologne

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