

TÜV Rheinland / CCIC (Qingdao)

6F Flat B, Fu Tai Plaza, 18 Hong Kong Middle Rd.,
Qingdao 266071, P.R. China

Attachment to

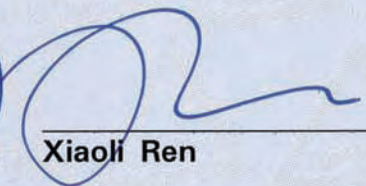
Registration No.: SY 50123980 0001
Report No.: 15024196 001

Manufacturer: Chison Medical Imaging Co., Ltd.
No. 8, Xiang Nan Road
Shuo Fang, New District
Wuxi, Jiangsu 214142
P.R. China

Scope: Manufacturing and Distribution of
Ultrasound Diagnostic Systems

Qingdao, 30.01.2008





Xiaoli Ren

APPROVAL

EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60019637 0001

Report No.: 15024196 001

Manufacturer: CHISON Medical Imaging Co., Ltd.
No. 8, Xiang Nan Road
Shuo Fang, New District

Wuxi 214142
China

Scope: Manufacturing of Ultrasound Diagnostic Systems
Replaces Approval, Registration No.: DD 60003925 0001

Date of Expiry: 06.12.2012

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 25.01.2008

Notified Body



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

Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

CHISON Medical Imaging Co., Ltd.
No. 8, Xiang Nan Road
Shuo Fang, New District

Wuxi 214142
China

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

**Manufacturing and Distribution of Ultrasound
Diagnostic Systems**

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 60019638 0001

An audit was performed. Report No.: 15024196 001

This Certificate is valid until: 06.12.2012

Certification Body

Cologne, 25.01.2008



Dipl.-Ing. U. Frenkert
Certifizierungsstelle

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

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TÜV Rheinland / CCIC (Qingdao)

6F Flat B, Fu Tai Plaza, 18 Hong Kong Middle Rd., Qingdao 266071, P.R. China

C E R T I F I C A T E

for a

Quality Management System

according to

EN ISO 13485:2003

TÜV Rheinland / CCIC (Qingdao) hereby certifies that the

Manufacturer: Chison Medical Imaging Co., Ltd.
No. 8, Xiang Nan Road
Shuo Fang, New District
Wuxi, Jiangsu 214142
P.R. China

has established and maintains a quality management system. Conformance with the requirements of the standards has been audited.
The organization is subject to a yearly surveillance audit.

Registration No.: SY 50123980 0001

Report No.: 15024196 001

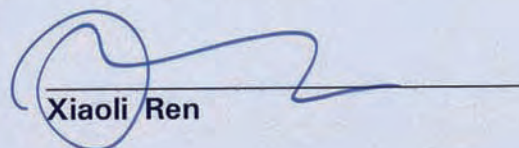
Date of expiry: 06.12.2012

Scope: refer to Attachment

Qingdao, 30.01.2008



Certification Body


Xiaoli Ren