TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60079620 0001

Report No.: 15054160 001

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

Products:
Ultrasound Diagnostic Systems

(see attachment for additional site included)

Replaces Approval, Registration No.: DD 60019637 0001

Expiry Date: 2017-11-14

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2012-11-20

Date: 2012-11-20

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60079620 0001
Report No.: 15054160 001

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

Site included:

No. 9, Xin Hui Huan Road, New District,
Wuxi 214028, P.R.China

Notified Body

Date: 2012-11-20

X. Ren