

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**GE Medical Systems
(China) Co., Ltd.**
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

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

**Design and Development, Manufacture and Distribution of
Medical Devices**
(see attachment for products and additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date: 2017-12-20
Certificate Registration No.: SX 60123505 0001
An audit was performed. Report No.: 15094484 005
This Certificate is valid until: 2020-06-30

Certification Body



Date 2017-12-20

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60123505 0001
Report No.: 15094484 005

Organization: GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

Scope:

Products:

- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
9900 Innovation Drive, Wauwatosa, WI 53226, USA

**Manufacture and Distribution of Ultrasound Diagnostic
Systems**

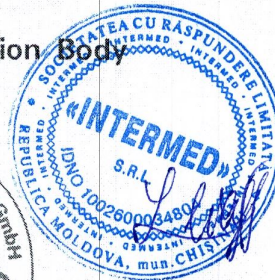
GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech
Development Zone, Jiangsu 214028, P.R.China

Storage and Distribution of Ultrasound Diagnostic Systems
and Probes, Anesthesia Devices, Bone Densitometry Systems,
ECG Module

Certification Body



Date: 2017-12-20



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60116081 0001

Report No.: 15094929 004

Manufacturer: GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60110059 0001

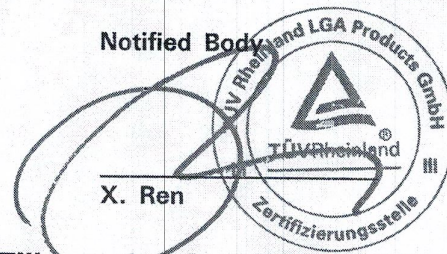
Expiry Date: 2021-05-02

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-01-03

Date: 2017-01-03

Notified Body



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



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
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Registration No.: HD 60116081 0001
Report No.: 15094929 004

Manufacturer: GE Medical Systems
(China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu
China

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Manufacture of Ultrasound Diagnostic Systems

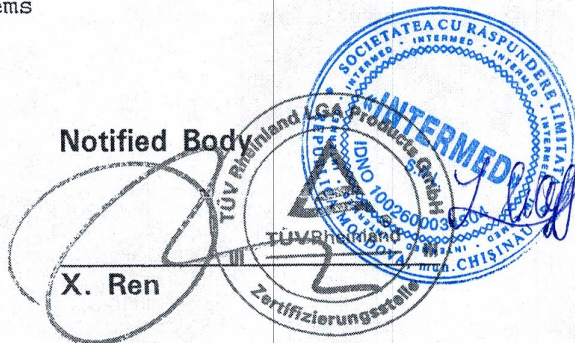
GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech
Development Zone, Jiangsu 214028, P.R.China

Storage of Ultrasound Diagnostic Systems

Date: 2017-01-03

Notified Body

X. Ren





TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.1

**Attachment to
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Development Zone, Jiangsu 214028, P.R.China

Date: 2017-12-20

