EC Certificate

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

Registration No.: HD 60107257 0001

Report No.: 17050945 001

Manufacturer:
Shenzhen Landwind
Industry Co., Ltd.
Room 408-413, Block E, Bijing Bldg.
Jingtian Road,
518034 Futian District, Shenzhen
China

Products:
Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60109340 0001

Expiry Date: 2021-03-09

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: 2016-03-25

Date: 2016-03-25

TÜV Rheinland LGA Products GmbH Notified Body TÜVRheinland Zertifizierungsstelle

Liu

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60107257 0001
Report No.: 17050945 001

Manufacturer:
Shenzhen Landwind
Industry Co., Ltd.
Room 408-413, Block E, Bijing Bldg.
Jingtian Road,
518034 Futian District, Shenzhen
China

Products:

Ultrasound Diagnostic Scanners, X-ray Radiography Systems, Digital Flat Panel Detectors, Digital Mammography System

Site included:

Shenzhen Landwind Industry Co., Ltd.
Landwind Science & Technology Park, Honglong High-tech Industrial Area, Liyuan Industrial Area,
Langxin Community, Zhuanchang, Shiyan Town,
Bao'an District, Shenzhen 518108, China

Design, Development and Manufacture of Ultrasound Diagnostic Scanners, X-ray Radiography Systems, Digital Flat Panel Detectors, Digital Mammography System

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

Notified Body

Date: 2016-03-25

S. Liu