TÜVRheinland®

EC Certificate

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

Registration No.: DD 60137545 0001

Report No.: 17039550 008

Manufacturer:
Dongguan Kaiser Technology
Co., Ltd.
No. 81 Sanjiang Industrial District,
523462 Hengli Town, Dongguan, Guangdong
China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60113207 0001

Expiry Date: 2024-05-27

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: 2019-07-15

Date: 2019-07-15

Notified Body
TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

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.: DD 60137545 0001
Report No.: 17039550 008

Manufacturer:
Dongguan Kaiser Technology Co., Ltd.
No. 81 Sanjiang Industrial District,
523462 Hengli Town, Dongguan, Guangdong
China

Products:

Bone Drills (machine only), Orthopedic Reamers (machine only), Electrical Surgical Bone Saws (machine only), Surgical Lavage Units, Surgical Illuminators, Bone Cement Mixer Syringe, Warming and Cooling Therapy, Blanket Warming Units;

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Bone Cement Mixer, Torque Instruments Manual

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-07-15