EC Certificate

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

Registration No.: DD 60115147 0001

Report No.: 17039791 006

Manufacturer:
Guilin Woodpecker Medical
Instrument Co., Ltd.
Information Industrial Park
Guilin National High-Tech Zone
Guilin
541004 Guangxi
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60103021 0001

Expiry Date: 2019-09-15

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: 2016-11-29

Date: 2016-11-29

Notified Body

S. 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.2

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60115147 0001
Report No.: 17039791 009

Manufacturer:
Guilin Woodpecker Medical Instrument Co., Ltd.
Information Industrial Park
Guilin National High-Tech Zone
Guilin
541004 Guangxi
China

Products:

- Ultrasonic Surgical Systems
- Handpieces and Tips of Ultrasonic Surgical System
- Ultrasonic Scalers
- Handpieces and Tips of Ultrasonic Scalers
- Apex Locators
- Dental Handpieces
- Root Canal (Endodontic) Files
- Dental Instruments for use of Periodontal surgical
- Handpieces and Tips of Dental Instruments for use of Periodontal surgical
- Endo Motors
- Dental Implant Unit
- Ultrasonic Endo Activate Device

Notified Body

TÜV Rheinland LGA Products GmbH TÜV Rheinland® III Zertifizierungsstelle

S. Liu

Date: 2018-08-31