EC Certificate

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

Registration No.: DD 60137494 0001

Report No.: 17039791 013

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 60115147 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: 2019-07-16

Date: 2019-07-16

Notified Body

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60137494 0001
Report No.: 17039791 013

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 TÜVRheinland® Zertifizierungsstelle

Date: 2019-07-16

Fuxiu Sheng