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.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60115147 0001
Report No.: 17039791 007

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2017-05-10

S. Liu

WOODPECKER

桂林市啄木鸟医疗器械有限公司
GUILIN WOODPECKER Medical Instrument Co.,LTD.

File No.: ZMN/WI-04-773-02
Version: E

EC Declaration of Conformity

Manufacturer:

Guilin Woodpecker Medical Instrument Co., Ltd.

whose single Authorized Representative:

MedNet GmbH•Borkstrasse 10 • 48163 Muenster • Germany

We, the manufacturer, herewith declare
that the products **Curing Lights** , *UMDNS-Code:* **18221**

MODEL:LED.B / LED.C / LED.D / LED.E / LED.F / LED.G / LED.H

BUILT–IN C / LUX V / LUX VI / LUX E / i Led

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

The product concerned has been manufactured under a quality management system according to Annex Ⅶ of Directive 93/42/EEC.

following the procedure relating to the EC Declaration of Conformity set out in Annex Ⅶ of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: **Guilin Woodpecker Medical Instrument Co., Ltd.**
Address: Information Industrial Park, GuiLin National High-Tech Zone, GuiLin, GuangXi, 541004, P.R.China

2016.11.29
Place, date

Legally binding signature, Function