EC Certificate

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

TÜVRheinland®

Registration No.: HD 60109212 0001

Report No.: 17050363 001

Manufacturer:
Foshan COXO Medical Instrument
Co., Ltd.
BLDG 4, District A
Guangdong New Light Source
Industrial Base, South of Luocun Avenue
Nanhai District
Foshan
528226 Guangdong
China

Products:
Medical Devices

(see attachment for products included)

Expiry Date: 2020-12-08

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: 2016-05-27

Date: 2016-05-27

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60109212 0001
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Products:

- Root Apex Locators
- Endo Motors
- Pulp Testers
- High-speed Air Turbine Handpieces
- Dental low speed handpieces including straight and geared angle handpieces and air-motors
- Dental Implant Systems

Date: 2016-05-27

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

S. Lutz