

EC Certificate

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

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

Products: China

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 - 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.



Doc. 1/1, Rev. 1

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.: HD 60109212 0001

Report No.: 17050363 002

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:

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

Date: 2017-05-12

