EC Certificate

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

Registration No.: DD 60151346 0001

Report No.: 17050363 010

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
P.R. China

Products:
Active dental devices
(see attachment for products included)

Replaces EC Certificate No. DD 60150762 0001

Expiry Date: 2024-05-26

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: 2020-12-06

Date: 2020-12-06

Notified Body

Shengkui Zhong

TÜVRheinland LGA Products GmbH
Zertifizierungsstelle

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. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60151346 0001
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Products:

- Root Apex Locators
- Endo Motors
- Pulp Testers
- High-speed Air Turbine Handpieces
- Straight Handpieces
- Geared Angle Handpieces
- Air Motors
- Dental Implantation Systems
- Dental Electrical Motors
- Endodontic Obturation Systems

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-12-06

Shengkui Zhong