

**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

**Products:** 528226 Guangdong  
P.R. China  
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 Zhang

**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.



# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 2182788-1

Organization: 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

Scope: Manufacture and Distribution of Root Apex Locators, Endo motors, Pulp  
Testers, Dental handpieces, Dental Implantation Systems, Dental Electrical  
Motors, LED Curing Lights, Dental Alginate mixers, Amalgamators, Gutta  
Cuts, Caries Detection Devices, Endodontic Obturation Systems, Dental  
Operating Lights

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10918988-100  
Effective date: 2021-12-09  
Expiry date: 2024-12-08  
Issue date: 2021-12-03



Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02



A handwritten signature in blue ink, likely belonging to Dipl.-Ing. W. Hsu.

Dipl.-Ing. W. Hsu  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



## WIDE SPECTRUM LED Curing Light Units

**X<sup>lite</sup>** 

### Technical Parameters:

Light source: 5W blue violet LED;  
Wavelength range: 385-515nm;  
Light intensity:  $>1,700\text{mW/cm}^2$ ;  
Battery: Lithium ion battery (battery full  
power running time: at least 90  
minutes)

### Power adapter

Input: 100-240V AC 50/60Hz

Output: 5V DC 1A

Charger time: About 90 minutes.



### Order code:

white-10311 black-10312 pink-10313



## LED Curing Light Units

**X<sup>lite</sup>** 

### Technical Parameters:

Light source: 5W CREE LED;  
Wavelength range: 420-490nm;  
Light intensity:  $>1,300\text{mW/cm}^2$ ;  
Battery: Lithium ion battery (battery full  
power running time: at least 60  
minutes)

### Power adapter

Input: 100-240V AC 50/60Hz

Output: 5V DC 1A

Charger time: About 60 minutes.

Can also buy 2 kinds of light guides for different  
clinical operation:



The diameter of 6mm  
90° tapered light guide

The diameter of 8mm  
120° short light guide

### Order code:

white-10411 black-10412

