

# EC Declaration of Conformity

according to the Regulation (EU) 2017/745

**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  
Tel: +86 (757) 66692058 Fax: +86(757)81800058  
Web: www.coxotec.com Email: coxotec@163.com  
SRN: CN-MF-000001682  
**Trademarks:** COXO, YUSENDEMENT, YSDENT, CODENTAL

**EC Representative:** **Lotus NL B.V. located**  
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.  
E-mail: [peter@lotusnl.com](mailto:peter@lotusnl.com)

**We declare under our sole responsibility that**

**the medical  
device(s)  
of class**

Product Name: Dental Operating Lights  
Model: CX249-21, CX249-22, CX249-23, CX249-24  
Basic UDI-DI: no, applying  
Class I , rule 13  
according to annex VIII of Regulation (EU) 2017/745  
(*non-sterile, non-measurement, non-reusable surgical*)

**meets the provisions of the Regulation (EU) 2017/745**

The products comply  
with requirements of  
relevant harmonized  
standards:

EN 60601-1:2006+ A11:2011+ A1:2013+A12:2014	EN 60601-1-2:2015
EN ISO 14971:2012	EN ISO 15223-1:2016
EN 1041:2008+A1:2013	EN ISO 9680:2014

Conformity  
assessment route:

Annex II+ III

Notified Body:

N/A

Signed this Day/ 25 of Month/ 05 of Year/ 2021 , Place (FoShan), PR China

**Represented by:**

Title: General Manager

Name: (Mr) Zheng Yongliang

Signature:

Official Seal:

