

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

We declare under our sole responsibility that

the medical device(s) of class Product Name: LED Curing Lights
Model: DB686, DB686 Latte, DB686 Deli, DB686 Ib, DB686 Super-Lux,
DB686 Super-Dual, DB686 Penguin, DB686 NANO, DB686 Swift
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 10650:2015

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:

