

EC Declaration of Conformity

according to the Regulation (EU) 2017/745

Manufacturer : **Foshan COXO Medical Instrument Co., Ltd.**
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SRN: CN-MF-000001682

Trademarks: COXO, YUSENDEMENT, YSDENT, CODENTAL

Lotus NL B.V. located

EC Representative: 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)**

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

of class

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:

