

EC Declaration of Conformity

according to the Regulation (EU) 2017/745

Manufacturer: **Foshan COXO Medical Instrument Co., Ltd.**
No. 17, Guangming Ave., New Light Source Industrial Base, Nanhai
National High-tech Zone, Foshan 528226, Guangdong P.R. China
Tel: +86 (757) 66692058 Fax: +86 (757) 81800058
Web: www.coxotec.com Email: coxotec@gmail.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) 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,
DB686 Helen+, DB686 Honor, DB686 Halo
Basic UDI-DI: 69742678901ZQ

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:

EN60601-1:2006+A1:2013+A2:2021	EN60601-1-2:2014+A1:2021
EN ISO 14971:2019+A11:2021	EN ISO 15223-1:2021
ISO 20417:2021	EN ISO 10650:2015

Conformity assessment route: Annex II+ III

Notified Body: N/A

Signed this Day/ 06 of Month/ 04 of Year/ 2024 , Place (FoShan) , PR China

Represented by:

Title: General Manager

Name: (Mr.) Zheng Yongliang

Signature:

Official Seal:

