EC Declaration of Conformity

according to the Regulation (EU) 2017/745

Manufacturer: **Foshan COXO Medical Instrument Co., Ltd.**
Site 1: BLDG 4, District A Guangdong New Light Source Industrial Base, South of Luocun Avenue Nanhai District Foshan 528226 Guangdong China
Site 2: 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@163.com
SRN: CN-MF-000001682
Trademarks: COXO, YUSENDENT, 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: Air Abrasion System with spray
Model: CA-1
Basic UDI-DI: 697426789084Q6

of class Class I, rule 5
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 ISO 13485:2016	EN ISO 14971:2019
EN ISO 20608:2018	ISO 15223-1:2021
EN 1041:2008+A1:2013	

Conformity assessment route: Annex II+ III

Notified Body: N/A

Signed this Day/ 05 of Month/ 05 of Year/ 2022 , Place (FoShan), PR China

Represented by:

Title: General Manager
Name: (Mr) Zheng Yongliang
Signature:
Official Seal: