

# 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](http://www.coxotec.com)      Email: [coxotec@163.com](mailto: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](mailto:peter@lotusnl.com)

**We declare under our sole responsibility that**

**the medical  
device(s)**

Product Name: File Removal System

Model: C-FR1

Basic UDI-DI: 697426789102PF

**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 1041:2008+A1:2013

ISO 15223-1:2021

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:

