

EC Declaration of Conformity

according to the Regulation (EU) 2017/745

Manufacturer:

Foshan COXO Medical Instrument Co., Ltd.

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South of Luocun Avenue Nanhai District Foshan 528226 Guangdong
China

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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: 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:

