



EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC



Manufacturer :

Foshan Coxo Medical Instrument Co., Ltd
 BLDG 4, District A, Guangdong New Light Source Industrial Base,
 South of Luocun Avenue, Nanhai District, Foshan, 528226 Guangdong,
 China
 Tel: +86 (757) 66692058 Fax: +86(757)81800058
 Web: www.coxotec.com Email: coxotec@163.com

EC Representative:

Wellkang Ltd
 The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

We declare under our sole responsibility that

**the medical
 device(s)
 of class**

Product Name : Dental Microscope
 Model : C-CLEAR-1, C-CLEAR-2
 Class 1 , rule 1
 according to annex IX of directive 93/42/EEC
(non-sterile condition, non-measuring function)

meets the provisions of the directive 93/42/EEC as amended by Directive 2007/47/EC and its transpositions in national laws which apply to it.

The products comply with requirements of relevant harmonized standards:

IEC 60601-1:2005+A12:2014	IEC 60601-1-2:2014
EN ISO 14971:2012	EN ISO 15223-1:2016
EN 1041:2008+A1:2013	

Conformity assessment route:

Annex VII (Section VII.5 not applicable)

Notified Body:

No

Signed this Day/ 07 of Month/ 05 of Year/ 2020 , Place (FoShan) , PR China

Represented by:

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

Official Seal:

