



# EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC



**Manufacturer :**

**Foshan Coxo Medical Instrument Co., Ltd**  
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**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:

