

# Declaration of Conformity

**We, Zumax Medical Co., Ltd.**

Address: 5 Zhiying Street , Suzhou New District, Suzhou, Jiangsu Province 215129,PR China

Tel: +86-512-66903235 Fax: +86-512-66909655

Website: [www.zumaxmedical.com](http://www.zumaxmedical.com)

**Declare on our sole responsibility, that the medical devices:**

Name: Colposcope

Model: CLS3080

meets all applicable requirements of the Directive 93/42/EEC Annex I, as amended by Directive 2007/47/EC

Applied standards :

IEC 60601-1: 2005 + CORR. 1 (2006) + CORR.  
(2007) and/or EN 60601-1:2006+A11:2011  
EN 60601-1-2:2015  
EN ISO 14971:2007  
ISO 15223:2012

Classification:

Classified as class I according to Annex IX,  
rule12 of the Directive 93/42/EEC.

Conformity assessment procedure:

Conformity assessment was performed according  
to Annex VII of the Directive 93/42/EEC.

The Authorized Representative within the EU  
who has been empowered to enter into  
commitments on our behalf is:

MedNet GmbH  
Borkstrasse 10  
48163 Münster, Germany

Date of issue: 15 /(Day) Mar /(Month) of 2019.

Place of issue: Suzhou , China

Signature (of authorized person



Typed name (of authorized person :) Xiangdong Li

Position/Title:

CEO

Stamp/Seal:

