

Declaration of Conformity

We, Zumax Medical Co., Ltd.

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Declare on our sole responsibility, that the medical devices:

Name: Colposcope

Model: CLS3020

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

Applied Standards

EN 60601 1:2006+AM1(2013)+A12:2014

EN 60601 1 2:2015

EN ISO 14971:2007

ISO 15223:2012

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

Classification:

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

Conformity assessment procedure:

MedNet EC-REP GmbH
Borkstrasse 10
48163 Münster, Germany

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

Date of issue: 21/(Day) February /(Month) of 2020.

Place of issue: Suzhou , China

Signature (of authorized person :)



Typed name (of authorized person :) Xiangdong Li

Position/Title: CEO

Stamp/Seal:

