CE

Declaration of Conformity

The following product is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Medical Devices Directive (93/42/EEC) and are Class I Medical Devices. The listed standards as below were applied:

The following Equipment:

Product : Colposcope
Model Number : AC-1000(Including AC-1100,1110,1300,1310,1320)
Trade Name : ALLTION
Medical Devices : Class I

This product is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Medical Devices Directive (93/42/EEC)and are Class I Medical Devices. For the evaluation regarding EMC ,the following standards were applied:

RFI Emission:

EN 60601-1-2: 2001	:	Product family standard
IEC 61000-3-2: 2005	:	Limits for harmonic current emission
IEC 61000-3-3: 2002	:	Limitation of voltage fluctuation and flicker in low-voltage supply system

Immunity:

EN 60601-1-2: 2001	:	Product family standard

The following importer/manufacturer is responsible for this declaration:

Company Name : ALLTION (WUZHOU)CO., LTD.
Company Address : SUITE B, 11/F., LIJING TOWER, CATHAY PLAZA, NO.18, ZHONGSHAN ROAD, WUZHOU, GUANGXI, CHINA
Telephone : +86-774-2836101 Facsimile: +86-774-2836192

Person is responsible for marking this declaration:

Wellkang Ltd t/a Wellkang Tech Consulting
Suite B,29 Harley Street, London W1G 9QR,England,United Kingdom

LION CHEN	CEO
Name (Full Name)	Position/ Title
September 11,2017	梧州奥顺贸易有限公司 ALLTION (WUZHOU) CO., LTD.
Date	Legal Signature

QuieTek Corporation

QTK No.: 075S019-IT-CE-P02V02

CE

Statement of Conformity

This certifies that the following designated product:

Product	:	Colposcope
Model Number	:	AC-1000 (Including AC-1100,1110,1300,1310,1320)
Trade Name	:	ALLTION
Company Name	:	ALLTION (WUZHOU)CO., LTD.

This product is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Medical Devices Directive (93/42/EEC)and are Class I Medical Devices. For the evaluation regarding EMC, the following standards were applied:

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Immunity:

EN 60601-1-2: 2001	:	Product family standard

DNV

NVLAP

NVLAP Lab Code : 200743-0

CNLA

1596

TEST LABORATORY

Gene Chang /President

The verification is based on a single evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test lab. Logo.