

EC Declaration of Conformity

We, Alltion (Guangxi) Instrument Co., Ltd., company address: NO.10, 3rd Road, Wuzhou industrial Park, Wuzhou, Guangxi, China. hereby declare under our own responsibility that the following product:

Product Name: Colposcope AC-1000 Series Model Number: AC-1110, AC-1310, AC-1320

Category: CLASS I

meets the provisions of the Council Directive 93/42/EEC, 2007/47/EC and the essential requirements which apply to it. Listed product was tested by Laboratory Shenzhen Huatongwei International Inspection Co., Ltd pursuant to applicable test procedures and complies with the requirements of IEC 60601-1-2: 2014 and IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012.

Certificate No.: CTS18090330 R/C:38882 IEC 60601-1-2 Certificate No.: CTE18090090 R/C:91590

The above mentioned device has been classified as class I devices according to rule 12 of Annex IX of the Directive 93/42/EEC and 2007/47/EC. This declaration is supported by the Quality Management System certification, certificate reference number: 41532 issued by NQA. This declaration is based on the conformity assessment of products to the requirements of Annex VII.



This Declaration is valid for all products concerned bearing the CE mark and manufactured by following "Manufacturer":

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Company Address: NO.10, 3rd Road, Wuzhou industrial Park, Wuzhou, Guangxi, China.

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> CHEN LIN CEO Name (Full Name) Position/Title For and on behalf of ALLTION (GUANGXI) INSTRUMENT CO., LTD. October 23,2020 Legal Signature

European Authorized Representative: Obelis s.a.

Date

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Representative: Mr. Gideon ELKAYAM (CEO)

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