

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-2000 Series
Model Number: AC-2311DA, AC-2311, AC-2110, AC-2111, AC-2121, AC-2310,
AC-2320, AC-2321, AC-2110DA, AC-2111DA, AC-2120DA,
AC-2121DA, AC-2310DA, AC-2320DA, AC-2321DA
Category: CLASS I

meets the provisions of the Council Directive 93/42/EEC and 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.

IEC 60601-1 Certificate No.: CTS18090329 R/C:96412
IEC 60601-1-2 Certificate No.: CTE18090089 R/C:52419

The abovementioned 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":

Company Name : Alltion (Guangxi) Instrument Co., Ltd.
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CHEN LIN
Name (Full Name)
October 23, 2020
Date

CEO
Position/ Title

For and on behalf of
ALLTION (GUANGXI) INSTRUMENT CO., LTD.
广西奥顺仪器有限公司

Legal Signature
Lion Chen
Authorized Signature(s)

European Authorized Representative:

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Representative: Mr. Gideon ELKAYAM (CEO)