

Declaration of Conformity

We, Alltion (Guangxi) Instrument Co., Ltd.

Address: No.10, 3rd Road, Wuzhou Industrial Park, Wuzhou City, Guangxi Province, China.

Website: <http://www.alltion.com>

Declare on our sole responsibility, that the medical devices:

Name: Colposcope

Model: AC-1110, AC-1310, AC-1320

Basic UDI-DI: 697044351AC1000XP

meets all applicable requirements of the Regulation (EU) 2017/745.

Applied standards: IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007 +A1:2012
EN 60601-1:2006+A1:2013
IEC 60601-1-2:2014
EN 60601-1-2:2015
ISO 14971:2019
ISO 15223-1:2021

Classification: Classified as class I according to Annex VIII,
rule13 of the Regulation (EU) 2017/745.

The Authorized Representative within the EU Obelis s.a.
Who has been empowered to enter into Bd. General Washis 53 1030
Commitments on our behalf is: Brussels, BELGIUM

Date of issue: 21/(Day)October/(Month) of 2021

Place of issue: Guangxi, China

Signature of authorized person:

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


Authorized Signature

Position/Title: CEO