

**EU DECLARATION OF CONFORMITY**

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**SRN (Single Registration Number):**

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BE-AR-000000106

**SRN (Single Registration Number):**

We, Alltion (Guangxi) Instrument Co., Ltd. hereby declare under our sole responsibility that the devices listed in the attached Annex comply with the provisions of the REGULATION (EU) 2017/745.

The devices are Class I following Rule 13 of Annex VIII of REGULATION (EU) 2017/745.

The Conformity Assessment Procedure has been performed following MDR Article 19 and Article 52(7), and Technical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.

The following Standards have been used and in relation to which conformity is declared:

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

The present declaration is in conformity with Regulation (EU) 2017/745.

**PRRC Signature:**

*Yuangang Jiang*  
Yuangang Jiang

**Position:** Vice General Manager

**Place of Issue:** Guangxi, China

**Date of Issue:** Jun 30,2022



**Annex - List of Devices Covered by the Declaration of Conformity**

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/ EMDN code
1	AC-2000 Colposcope	AC-2110 AC-2111 AC-2120 AC-2121 AC-2310 AC-2311 AC-2320 AC-2321 AC-2110DA AC-2111DA AC-2120DA AC-2121DA AC-2310DA AC-2311DA AC-2320DA AC-2321DA	Be used for magnification and illumination of gynecological microsurgery	The ALLTION Colposcope is a device designed for viewing of the tissues of the vagina and cervix by a telescopic system located outside of the vagina. A colposcope is used to diagnose and examined abnormalities of the vagina and cervix.	I	Rule 13	697044351 AC2000XW	10960