

EU DECLARATION OF CONFORMITY

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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 60601-1-2:2014+A1:2020
EN 60601-1-2:2015+A1:2021
IEC 60601-1:2005+A1:2012+A2:2020
EN 60601-1:2006+A1:2013+A12:2014+A2:2021
ISO 14971:2019
ISO 15223-1:2021

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

PRRC Signature:

Jian Chen
Jian Chen



Position: Quality Department Manager

Place of Issue: Guangxi, China

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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	YDJ Colposcope	YDJ-II (AC-4501) YDJ-II-1(AC-4503) YDJ-Z(AC-4601)	Be used for magnification and illumination of gynecological microsurgery	The YDJ Colposcope are featured for sharp image, wide field of view, uniform illumination, adjustable brightness and easy operation. They are the essential instruments for gynecologic examination.	I	Rule 13	69704435 1YDJRL	GMDN:10 960 EMDN: Z1202070 3