



EC Declaration of Conformity



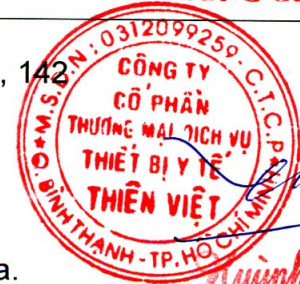
according to the Medical Devices Directive 93/42/EEC

Class I Medical Device
(non-sterile, non-measuring function)

Manufacturer: Xuzhou AKX Electronic Science and Technology Co., Ltd

Address: C1-1-11 Mingyang Square, Economic Development Zone, Xuzhou City 221005 Jiangsu Province, China

EC Representative: ENDOMED SRLS
C/O Centro Ziqurat Via Appia Lato Napoli, 142
04023 Formia (LT)-Italy



We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	: Endoscope Camera.
of class	Type/model, identification of product allowing traceability (Where applicable)	: YKD-9109 (YKD-9003), YKD-9119 (YKD-9003), YKD-9122 (YKD-9003), YKD-9100 (YKD-9003), YKD-9003 (YKD-9100)
	according to annex IX of directive 93/42/EEC	: Class I

is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.

Applied harmonised standards, national standards or other normative documents	IEC 60601-1-2:2014	IEC 60601-2-18:2015
	IEC 60601-1-2:2015	IEC 62471:2006
	IEC 60601-1:2005+A1:2012	IEC 62471:2008
	IEC 60601-1:2006+A1:2013	
	IEC 60601-2-18:2009	

Conformity assessment procedure: Module A (EC Declaration of Conformity (Annex VII) + Technical Files)

Notified Body (name & number) Certificate & number: NOT applicable

Signed on 18 / 11 / of 2019. Place: Xuzhou, PR China

Signature (on behalf of the manufacturer) :

Name of authorized signatory: Xu Shanhua

Position held in the company: General Manager

