Digitally signed by Timuş Andrei
Date: 2023.06.10 09:55:01 EEST
Reason: MoldSign Signature
Location: Moldova

CE CE

EC Declaration of Conformity

according to the Medical Devices Regulations MDR（EU2017/745）

Class I Medical Device

(non-sterile, non-measuring function,non-reuse)

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

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

EC Representative: TEOTRONIK MEDICAL SAS
Via Palermo,4 – 95030 Pedara (CT) - ITALY

We, the manufacturer, declare under our sole responsibility that

Product Name：FULL HD Endoscope system

Medical device(s)

Type/model：YKD-9100、YKD-9101、YKD-9102、YKD-9103 YKD-9107、YKD-9122、YKD-9001

According to annex Ⅷ of directive MDR(EU2017/745)： Class Ⅰ

EU product code：35958

Identification of product Allowing traceability：UDI Not in use

is/are in conformity with the relevant provisions and requirements of Regulations MDR（EU2017/745）

Applied harmonised standards, national standards or other normative documents

IEC 60601-1-2:2014

EN 60601-1-2:2015

IEC 60601-1:2005+CORR.2:2007+A1:2012

EN 60601-1:2006+A1:2013+A12:2014

Conformity assessment procedure: According to MDR(EU2017/745) Article 52 (Annex Ⅱ +AnnexⅢ)

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

Signed on 26 / 05 / of 2021. Place: Xuzhou PR China

Signature (on behalf of the manufacturer)：

Name of authorized signatory: Xu Shanhua

Position held in the company: GeneralManager