



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

Manufacturer

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel,
The Netherlands.
SRN: NL-AR-000000247

Name: Xuzhou AKX Electronic Science and Technology co., Ltd
Address: C1-1-11 Mingyang Square, Economic Development
Zone Xuzhou 221005 Jiangsu P.R. China
SRN: CN-MF-000031488

Product Information

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU)
2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN 60601-1-2:2015+A1:2020
EN 60601-1:2006+A1:2013
IEC 60601-2-18:2009

Name: Endoscope Camera

(FULL HD Endoscope System;4K Medical Endoscope Camera
System)

Model:

YKD-9001;YKD-9002;YKD-9003;YKD-9006;YKD-9007;YKD-9001E;YK
D-9020;YKD-9021;YKD-9100;YKD-9101;YKD-9102;YKD-9103;YKD-9
105;YKD-9106;YKD-9107;YKD-9103E;YKD-9103E-T, YKD-9107E,
YKD-9107E-T;YKD-9115;YKD-9119;YKD-9122;YKD-9124;YKD-9127;
YKD-9127F;YKD-9132;YKD-9132F;YKD-9155;YKD-9155F;YKD-9115
E, YKD-9115T;YKD-9119D; YKD-9119T; YKD-9210;YKD-9211

EMDN: Z12020405

Basic UDI-DI: 697378758SMNK9000SX

Classification: Class I, According to Rule 13, Annex VIII,
Regulation (EU) 2017/745

Declaration

Remark

*The declaration of conformity is valid in
connection with the release technical
document CE/MDR- Z12020405 -01.*

*All the supporting documentation is
retained at the premises of the
manufacturer.*

*The Declaration of Conformity is
exclusively under the sole responsibility
of the manufacturer.*

We herewith declare that the above-mentioned products meet the
requirements of Medical Device Regulation (EU) 2017/745 and the
applicable standards above.

Signature:

[Handwritten Signature]

Date:

2022.10.27

Position: GM



Place: Xuzhou/China