DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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

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
ISO13485: 2016

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z12020402-04.

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.

Manufacturer

Name: Wuzhou Aokace Technology Co., Ltd.
Address: Buidling 10, Yingtian Industrial Park, High-tech Industrial Development Zone, Wuzhou, Guangxi, China
SRN: CN-MF-000027213

Product Information

Name: Cold light source
Model: AGS210、AGS200、AGS100 、AGS-PL100
EMDN: Z12020402
Basic UDI-DI: 697546580AGSCLSS5
Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Declaration

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

Signature:
Position: GM

Date: June 1st, 2023
Guo Qinping
Place: Guangxi/China