



## 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

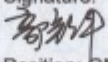
Name: Wuzhou Aokace Technology Co., Ltd.  
Address: Buidling 10, Yingtian Industrial Park,  
High-tech Industrial Development Zone, Wuzhou,  
Guangxi, China  
SRN: CN-MF-000027213

### 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

