



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Cert GmbH

Harffstr. 47,40591 Düsseldorf,  
Germany

SRN: DE-AR-000010869

## 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  
IEC 60601-1:2012  
IEC60601-1-2:2014  
IEC60601-2-41:2013

## Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Z120107-01.*

*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.*

## Manufacturer

Name: HUNAN MPLENT OPTOELECTRONICS  
TECHNOLOGY CO.,LTD

Address: NO.15,Liujiao Pavilion Road,Langli  
Street,Changsha City,Hunan Province,China

SRN:

## Product Information

Name: SURGICAL LIGHT

Model: ZW-700/500E, ZW-700/700E, ZW-700E,

ZW-500E, ZW-500E(L), ZW-700/500D, ZW-700/700D,  
ZW-700D, ZW-500D, ZW-500D(L),ZW-K700/500H,  
ZW-K700/500, ZW-K700/700H, ZW-K700/700,

ZW-K500/500H, ZW-K500/500, ZW-K700H, ZW-K700,  
ZW-K500H,ZW-K500, ZW-K700H(L), ZW-K700(L),  
ZW-K500H(L),ZW-K500(L),

ZW-G700/500, ZW-G700/700, ZW-G500/500,  
ZW-G700, ZW-G500,ZW-G700(L), ZW-G500(L),

ZZ-A250L, ZZ-A250J, ZZ-A250D, ZZ-A250B,  
ZZ-B400/400(bat),ZZ-B400/400,ZZ-B400(bat),ZZ-B400,  
ZZ-B400L(bat),ZZ-B400L

EMDN: Z120107

Basic UDI-DI: /

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:

Date:



Position: GM

Place: Hunan/China