

# EU DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION



## Manufacturer

**Name:** RUIAN SUNNYWORLD  
INTERNATIONAL TRADE CO.,LTD.

**Address:** No.3, Sanxiang, Gaoyang Road,  
Ruian city, Zhejiang Province, China

## EU Representative

Luxus Lebenswelt GmbH [DE]

Kochstr 1, Willich, Germany,  
47877

## Product information

**Name:** PENLIGHT

**Model:** SW-PL01,SW-PL07,SW-PL16,SW-45,SWPL48,SW-PL49,SW-PL78,SW-PL37

**GMDN:** 38832

**Basic UDI:** 697278932PEN006RK

**SRN:** /

**Classification:** Class I

For and on behalf of  
 **LUXUS LEBENSWELT GMBH**  
Kochstr.1, 47877 Willich, Germany



Only used for EU Representative Agreements

## Conformity Assessment

### Conformity Assessment Procedure:

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

### Applicable Standards:

EN ISO14971:2019; EN ISO15223-1:2016; EN1041:2016; EN60601-1:2012

EN60601-1-2:2015; ISO10993-5:2009; ISO10993-10:2010

## Declaration

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

The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Place: Ruian/China

Date: 2022.05.01

Signature: 

Position: GM

