



## DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

### EU Representative

SUNGO Europe B.V.  
Olympisch Stadion 24, 1076DE  
Amsterdam, 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 60601-2-41:2009+A11:2011+A1:2015  
EN  
60601-1:2006+A1:2013+AC:2014+A12:2014  
+A2:2020  
EN 60601-1-2:2015+A1:2020

#### Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z129004-01.

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: Nanchang Micare Medical Equipment Co.,Ltd  
Address: Building 16th No.666 Yaohu West 5th Road, Hi-Tech Zone Nanchang, Jiangxi, China  
SRN: /

### Product Information

Name: Surgical Light  
Model: See annex  
GMDN: 12276  
EMDN: Z129004  
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: 2022/06/20

Position: GM Place: Jiangxi / China

## Annex

Product Name	Model
Surgical Light	E500, E500L, E500G, E700, E700L, E700G, E700/500, E700/700, E500/500 MK500, MK500L, MK500G, MK700, MK700L, MK700G, MK700/500, MK700/700, MK500/500 MR500, MR500L, MR500G, MR700, MR700L, MR700G, MR700/500, MR700/700, MR500/500 MKT500, MKT500L, MKT500G, MKT700, MKT700L, MKT700G, MKT700/500, MKT700/700, MKT500/500 MRT500, MRT500L, MRT500G, MRT700, MRT700L, MRT700G, MRT700/500, MRT700/700, MRT500/500 E520, E520L, E520G, E720, E720L, E720G, E720/520, E720/720, E520/520 E1, E1(G), E1(L), E2, E2(G), E2(L), E3, E3(G), E3(L), E4, E4(G), E4(L), E6, E6(G), E6(L), E1/1, E2/1, E2/2, E3/1, E3/2, E3/3, E4/1, E4/2, E4/3, E4/4, E500/1, E500/2, E500/3, E500/4, E6/1, E6/2, E6/3, E6/4, E6/500, E6/6, E700/1, E700/2, E700/3, E700/4, E700/6, Or customized

# Certificate of Registration



This is to certify that the Quality Management System of

## Nanchang Micare Medical Equipment Co., Ltd.

**Unified Social Credit Code:** 91360106576136496G

**Operation Address:** Building 16, No.666, Yaohu West 5th Road, Changdong Town, Hi-Tech Industrial Development Zone, Qingshanhu District, Nanchang City, Jiangxi Province, China

**Registered Address:** Building 16, No.666, Yaohu West 5th Road, Changdong Town, Hi-Tech Industrial Development Zone, Nanchang City, Jiangxi Province, China

applicable to

Manufacture and Sales of Overall Reflection Type Shadowless Operation Theatre Light, Medical Examination Light, Medical Headlights (without installation , within the scope of license)

has been assessed and registered by NQA against the provisions of

**ISO 13485:2016**

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website ([www.cnca.gov.cn](http://www.cnca.gov.cn))  
SNQA's website: [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director



015



Certificate Number

**44625**

Date:

02 April 2018

Previous Certificate Expiry:

02 April 2021

The Latest Audit Date:

11 April 2021

Reissue Date:

10 April 2024

Valid Until:

10 April 2026



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.

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applicable to

Manufacture and Sales of Overall Reflection Type Shadowless Operation Theatre Light, Medical Examination Light, Medical Headlights (without installation , within the scope of license)

has been assessed and registered by NQA against the provisions of

**ISO 9001:2015**

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

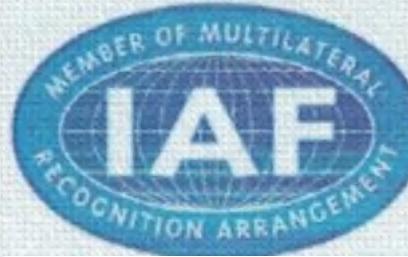
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Managing Director



015



Certificate Number

44624

Date: 02 April 2018  
Previous Certificate Expiry: 02 April 2021  
The Latest Audit Date: 11 April 2021  
Reissue Date: 24 May 2021  
Valid Until: 02 April 2026  
EAC Code: 19



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