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

Digitally signed by Antonova Anna
Date: 2025.10.22 11:43:38 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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)

SNQA's website: www.snqa.com.cn

Managing Director

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

015

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.

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 9001:2015

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)

SNQA's website: www.snqa.com.cn

Managing Director

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

UKAS MANAGEMENT SYSTEMS
015

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