



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	<p>E500, E500L, E500G, E700, E700L, E700G, E700/500, E700/700, E500/500</p> <p>MK500, MK500L, MK500G, MK700, MK700L, MK700G, MK700/500, MK700/700, MK500/500</p> <p>MR500, MR500L, MR500G, MR700, MR700L, MR700G, MR700/500, MR700/700, MR500/500</p> <p>MKT500, MKT500L, MKT500G, MKT700, MKT700L, MKT700G, MKT700/500, MKT700/700, MKT500/500</p> <p>MRT500, MRT500L, MRT500G, MRT700, MRT700L, MRT700G, MRT700/500, MRT700/700, MRT500/500</p> <p>E520, E520L, E520G, E720, E720L, E720G, E720/520, E720/720, E520/520</p> <p>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</p>