



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
60601-1:2006+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-Z129004-02.

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: CN-MF-000027991

Product Information

Name: Examination Lights
Model: See annex
GMDN: 32037
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

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Position: GM

Place: Jiangxi / China

Annex

Product Name	Model
Examination Lights	JD1000, JD1000L, JD1000J, JD1000G JD1001, JD1001L, JD1001J, JD1001G JD1002, JD1002L, JD1002J, JD1002G JD1003, JD1003L, JD1003J, JD1003G JD1005, JD1005L, JD1005J, JD1005G JD1006, JD1006L, JD1006J, JD1006G JD1008, JD1008L, JD1008J, JD1008G JD1009, JD1009L, JD1009J, JD1009G JD1100, JD1100L, JD1100J, JD1100G, JD1200L, JD1200G, JD1200J, JD1300L, JD1300J, JD1300G, JD1400L, JD1400J, JD1400G, JD1500J, JD1500L, JD1500G, JD1600J, JD1600L, JD1600G, JD1700J, JD1700L, JD1700G, JD1700, JD1800L, JD1800J, JD1800G, JD1900J, JD1900L, JD1900G, JD1800, JD1900, Or customized