



EU Declaration of Conformity

Manufacturer:

whose single Authorized EU-Representative:

ZOOMAX TECHNOLOGY CO., LIMITED

9F, Building D, Paradise Software Park,
No.3 Xidoumen Road, Xihu District,
Hangzhou, China 310012

SUNGO Europe B.V.

Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

SRN: CN-MF-000017637
Basic UDI-DI: 697043837EVM001JL
Product Name: Electronic Video Magnifier
Models: Snow 12, Luna 6, Luna 8

Classification (According to the Annex VIII of MDR): Class I, Rule 13, Annex VIII, Regulation (EU) 2017/745

Conformity Assessment Route: Chapters I and III of Regulation (EU) 2017/745

We herewith declare in our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EU regulation and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Regulation:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Applicable Standards:

EN ISO 14971: 2019	EN ISO 10993-1: 2020
EN ISO 15223-1: 2021	EN ISO 10993-5: 2009
EN ISO 20417:2021	EN ISO 10993-10: 2023
EN 60601-1-2:2015+A1:2021	EN ISO 10993-23: 2021
EN 60601-1:2006+A2:2021	

Signature: 

Name: Rebecca Chen

Place: Hangzhou, China

Title: CEO

Date: 18th. Dec. 2023

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