DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The Netherland
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO14971:2019
EN ISO15223-1:2016
EN 1041:2008+A1:2013
EN 62366-1:2015
EN ISO14889: 2013+A1:2017
EN ISO 8980-1:2017
EN ISO 8980-3:2013
EN ISO 21987:2017

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-SL-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: JIANGSU YOULI OPTICS SPECTACLES CO., LTD

Address: NO.18 South to Reservoir, Yiwei Road, Economic Development Zone,Danyang,Jiangsu,China
SRN:CN-MF-000011468

Product Information

Name: SPECTACLE LENSES
Model: 1.50, 1.56, 1.60, 1.67, 1.74
GMDN: 46290
Basic UDI-DI: 697473234lens2021019E
Classification: Class I, according to Rule1, 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.

JIANGSU YOULI OPTICS SPECTACLES CO., LTD 江苏省丹阳市 321181501240

Signature: Zhu Chuanchuan Date: 6/13/23

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Position: QC manager Place:Jiangsu, China