

Declaration of Conformity

Manufacturer: WENZHOU SUNRISE INDUSTRIAL AND TRADING CO., LTD
Address: Building#1, #1 Tonghui Road, Panqiao Street, Ouhai District, Wenzhou, Zhejiang,
325000, China
SRN: CN-MF-000043059

Product name: Optical Frame
Model(s): N/A
Basic UDI-DI: 697767960OPRZF
Type: Class I, rule 1, Annex VIII, chapter III
Conformity Assessment Route: Annex II and Annex III

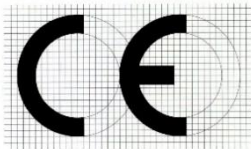
The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, EN ISO 15223-1:2021, EN 62366-1:2015, ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021, ISO 12312-1:2022, EN ISO 14889:2013+A1:2017, ISO 21987:2017

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative

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This declaration is issued under the sole responsibility of the manufacturer.

温州升蓝工贸有限公司
WENZHOU SUNRISE INDUSTRIAL AND TRADING CO.,LTD.



Signature of Authorized Person

Ann Yao

Title: Compliance manager

Place: Wenzhou City