DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert Gmbh

Harffstr. 47,40591 Düsseldorf, Germany

SRN: DE-AR-000010869

Conformity Assessment

Conformity Assessment Procedure

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

Applicable Standards

EN ISO14971:2019

EN ISO15223-1:2021

EN ISO 20417:2021

EN ISO12870:2016

EN ISO 21987:2017

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Q021001-01.

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: Wenzhou Flyer Import and Export Co,ltd

Address: B-1305 E-Business Mansion,Panqiao Street,Ningbo Road,Ouhai Area,WZ,ZJ,China

SRN:CN-MF-000024841

Product Information

Name: EYEGLASSES

Model: FY

EMDN: Q021001

GMDN: 35065

Basic UDI-DI:

metalframes	697542800metalframesPC
plasticframes	697542800plasticframesAE
Myopiaglasses	697542800MyopiaglassesLP
readingglasses	697542800readingglassesXX

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.

Signature: 陈志勇 Date: 2022.05.06

Position: GM Place: Wenzhou / China