

CERTIFICATE

Certificat - Certificado- Сертификат - Zertifikat - 證書

- 1) **APPLICANT:** (who finally puts the product on the market)
Wenzhou Cnova Optical Co., Ltd.
No.10 GaoZhan Road, GaoXiang Industry Zone, Wenzhou, Zhejiang, China
- 2) **CERTIFICATE NO.:** ISETC.002520200907
TECHNICAL REFERENCE: PL2008324 (Shenzhen Precision Eyewear Testing & Inspection Services Co.,Ltd.)
- 3) **ISSET MARK:**



- 4) **CAUTION ABOUT CE MARKING** (Instruction for the Applicant who puts the product on the EU market):

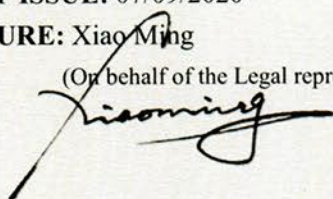


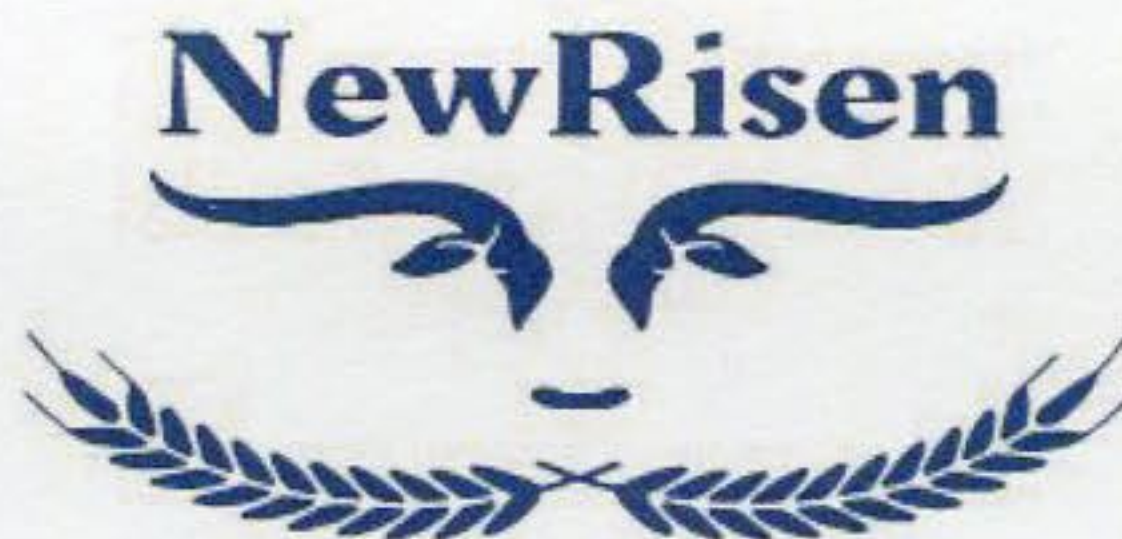
The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.

- 5) **TYPE OF PRODUCT:** Optical Frames
MODEL(S): Minions 14
- 6) **LIST OF DIRECTIVES / REGULATIONS /STANDARDS** (as declared by the manufacturer itself)
Medical Device Directive 93/42/EEC
EN ISO 12870:2018
- 7) **NOTE:** This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.
- 8) **REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.
- 9) **DATE OF ISSUE:** 07/09/2020
- 10) **SIGNATURE:** Xiao Ming

EXPIRY DATE: 06/09/2025

(On behalf of the Legal representative)





EU Declaration Of Conformity

Manufacturer:

Wenzhou Huishi Trading Co., Ltd.
Room 1006, Yueshang Mansion, Nanhui Street,
Lucheng District, Wenzhou, Zhejiang, China

SRN: CN-MF-000009539

Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

SRN: DE-AR-000005110

We, the manufacturer, herewith declare that the products

Product Name	Optical Frames
Brand	HUISHI
Model(s)	FE, FLEXY, HUISHI, HS
UMDN Code	15-582
Harmonized Standard	EN ISO 12870:2018
Basic UDI-DI	Product Group(s)
697454050FLEXYANT	Acetate Optical Frames
697454050FLEXYMPK	Metal Optical Frames
697454050FLEXYPPR	Plastic Optical Frames

meet the provisions of Regulation (EU) 2017/745 which apply to them.

The medical device has been assigned to class I according to Annex VIII of the Regulation (EU) 2017/745. It bears the mark



following the procedure relating to the EU Declaration of Conformity set out in Annex IX of Regulation (EU) 2017/745.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of Wenzhou Huishi Trading Co., Ltd.

Legally binding signature, Function

Linghe Shi

General Manager

Place: Wenzhou, China

Date: May 26th, 2021



CERTIFICATE

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DECLARATION OF CONFORMITY

This Declaration of Conformity is issued under the sole responsibility of the manufacturer

WENZHOU CNOVA OPTICAL CO., LTD.

*Address: 6th floor, Building 1, No. 83, Xueyuan Road, Louqiao Street, Ouhai district,
Wenzhou, Zhejiang Province, China*

Basic UDI-DI:

PRODUCT FAMILY	BasicUDI-DI
PLASTIC FULL RIM	697447937PFRYE
METAL FULL RIM	697447937MFRXX
MIXED FULL RIM	697447937PMFRW8
PLASTIC HALF RIM	697447937PHRYL
METAL HALF RIM	697447937MHRY5
MIXED HALF RIM	697447937PMHRWE
PLASTIC FULL RIM READING	697447937FRPRVR

Risk Class 1

We certify that the above model is in conformity with:

UK MDR 2002, Regulation (EU) 2017/745 and DIRECTIVE 93/42/EEC on medical devices
(EU MDD)

And consequently has successfully passed all requirements according to the latest version of
the following international standards:

BS EN ISO 12870:2018/BS EN 16128:2015/ASTM B117-16

Signature: Ariel Hu



Place of issue: China

Date of issue: 2022/01/20

Company Stamp:

温州优诺光学有限公司
WENZHOU CNOVA OPTICAL CO., LTD.



ISTITUTO SERVIZI
EUROPEI TECNOLOGICI

ISET S.r.l.

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Cap. soc. i.v.
Cod. Fisc. e P.IVA
Reg. Imprese
REA

€ 10.200,00
02 332 750 369
02 332 750 369
MN 0221098

CERTIFICATE OF COMPLIANCE

Certificado de Conformidade - Сертификат соответствия - Konformitätserklärung

1) APPLICANT:

Wenzhou Light Industrial Products Arts &
Crafts Import & Export Co., Ltd.
21-22/F International Trade Center Bldg., No.236
Liming West Road, Wenzhou, China

2) CERTIFICATE NO.:

IT091605LT160725

TCF(S) NO.:

LI-16000791

3) WITH REFERENCE TO EC DIRECTIVE APPLIED:

Medical Device Directive 93/42/EEC

4) CERTIFICATION ISET MARK:



HARMONIZED STANDARDS APPLIED:
EN ISO 12870:2014

5) PRODUCT CHARACTERISTICS: Spectacle Frames

MODEL(S): QG, WL

REMARK: The verification has been carried out on voluntary application of the manufacturer based only on the documents prepared and provided by the manufacturer itself. The product(s) satisfies the requirements of the Certification Mark of ISET according to the ISET regulations. The manufacturer is responsible to maintain the internal production control to ensure the compliance of the product. ISET declines any liability with reference to any other noncompliance of documents, product or test report that have been submitted to evaluation. However CE marking and EC declaration are duties of the manufacturer before putting into service of its product(s) on market. The manufacturer is required to appoint a Notified Body to get the CE Certification and meet all the necessary law requirements according to the Directive and accepted by the Notified Body.

6) DATE OF ISSUE: 25/07/2016

DATE OF EXPIRE: 24/07/2021

CERTIFICATION MANAGER:

