

User's Manual of Spectacles















Spectacles is non-sterile disposable anti-fog Spectacles.



1. Brand: Refine
2. Product name: Spectacles
3. Material: PC 100%
4. Model: EP03
5. Composition: composed of protective cover and fixing device made of polymer material. Non-sterile, single use.
6. Applied standards: GB 14866-2006 / EN166:2001 / ANSI/ISEA Z87.1-2015
AS/NZS 1337.1:2010 / CSA Z94.3-2015
7. Intended use : Spectacles is common eye protection equipment. Recommended industry: Facility Sanitation, Food Processing, Food Safety
8. Product instruction: The product and the protective packaging should be checked before using. Stop using it if there is any damage.
9. Precautions:
 - a. One-time use only.
 - b. Use in accordance with the instructions.
 - c. Never use it when damages are found.
 - d. Stay away from chemicals.
 - e. The eye protector is not intended to protect against high speed particles.
10. Storage: Please store in clean, dry and ventilated indoor place, with relative humidity (10%-93%), Atmospheric pressure for storage (70kPa-106kPa), temperature (-20°C- +40°C), avoid corrosive gas.

⚠ Warning:

- a. Materials which may come into contact with the wearer's skin could cause allergic reactions to susceptible individuals;
- b. Scratched or damaged oculars should be replaced;
- c. Eye-protectors against high speed particles worn over standard ophthalmic spectacles may transmit impacts, thus creating a hazard to the wearer.
- d. These protectors are intended for indoor use where no optical radiation hazards exist.

Symbol instruction

Symbol	Instruction	Symbol	Instruction
	Warning, Caution and Important ! Check the Instruction Manual		EU Representative
	Date of manufacture		Manufacturer
	Recovery		Handle with care
	Keep dry		Consult the accompanying documents
	Atmospheric pressure for storage		Single-Use
	Temperature limitation for storage		Lot number
	Humidity limitation for storage		MDEL certification

Symbol	Instruction	Symbol	Instruction
Z87	According to ANSI/ISEA Z87.1-2015	REFINE 1SN EN166 S	According to EN 166:2001, REFINE - manufacture 1 - Optical class (Class I) S - Symbol for increased robustness N - Symbol for Resistance to fogging of oculars EN 166 - Product Standards S - Symbol for Increased robustness
	EAC certification		
	CE certification		



Guilin Refine Medical Instrument Co., Ltd.

No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R. China



MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Shelf life: 2 Years

Applied standards: GB 14866-2006 / EN166:2001 / ANSI/ISEA Z87.1-2015

AS/NZS 1337.3:2010 / CSA Z94.3-2015



EU DECLARATION OF CONFORMITY

1. PPE (product, type, batch or serial number):

Spectacles, EP03, Category II, AZ631

2. Name and address of the manufacturer and, where applicable, his authorized representative:

Manufacturer: Guilin Refine Medical Instrument Co.,LTD.

Address of the manufacturer: No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R.China

Authorised representative: MedPath GmbH

Address of the Authorised representative: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer: Guilin Refine Medical Instrument Co.,LTD.

No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R.China

4. Object of the declaration (Identification of PPE allowing traceability; where necessary for the identification of the PPE a colour image of sufficient clarity may be included):



EP03:

Traceability Labeling:

Spectacles

Brand: Refine

Model: EP03

Lot No.: **AZ631**

Production Date: June 2020

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonization legislation: Regulation (EU) 2016/425

6. References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications; including the date of the specification, in relation to which conformity is declared:

Harmonised Performance Standard No(s): **EN 166:2001**

Technical specification No(s): **RF-EP3-T001**

Test Reports: **C80272046R001**

7. Where applicable, the notified body UL International (Netherlands) B.V. (European Notified Body No. 2821) performed the EU type-examination Module B and issued the EU type-examination certificate : **2821-PPE-0003.**

Signed for and on behalf of Guilin Refine Medical Instrument Co.,LTD.

(place and date of issue): **Guilin , 2020-06-07**

Name: Jordan Chen, Title: Management representative (signature):

Jordan Chen

