



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

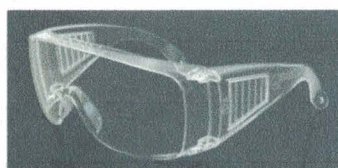
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

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

