



## EU DECLARATION OF CONFORMITY

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

**Safety Goggle, EP02, Category II, AZ821**

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):

EP02:



Traceability Labeling:

**Safety Goggle**  
Model: EP02



Scan the QR code to find the instruction. For further issue, please contact the manufacturer

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

MedNet EC-REP GmbH (Medical)  
Borkstrasse 10, 48163 Münster,  
Germany

MedPath GmbH (PPE)  
Mies-van-der-Rohe-Strasse 8,  
80807 Munich, Germany

Applied standards:  
GB 14866-2006 / EN 166:2001

ANSI/SEA Z87.1-2015

Shelf life: 2 Years

Lot No.: AZ821

Production Date: August 2020



合格证

本产品经检验合格，准予出厂！

产品品牌: Refine

产品名称: 医用防护镜

产品成分: PVC 70% PC 30%

规格型号: EP02

包装规格: 1个/套, 25个/盒, 10盒/箱

结构组成: 由高分子材料制成的防护罩和固定带

组成。非无菌提供，一次性使用。

执行标准: GB 14866-2006 / EN 166:2001

ANSI/SEA Z87.1-2015

适用范围: 用于医疗机构中治疗时的防护作用，阻隔体液、血液飞溅等。

生产日期: 2020年8月

有效期至: 2年

检验批: QC02

检验日期: 2020年8月

生产许可证编号: 桂桂食药监械生产许20170008号

备案凭证/产品技术要求编号: 桂械备2020014号

生产企业: 桂林玮德医疗器材有限公司

生产地址: 桂林市七星区高新区信息产业园8-3

号D-06号地块1#楼一层及2#楼D-6地块3栋1楼

两间及2、3、4楼; 灵川县大圩镇鹿村村委会

村(电话: 0854-1) 1楼厂房第一层

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-EP2-T001**

Test Reports: **C80602016**

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-0014**.

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

(place and date of issue): **Guilin, 2020-07-28**

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

*Jordan*