



EU DECLARATION OF CONFORMITY

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

Safety Goggle, EP05, Category II, AZ851

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):

EP05:



Traceability Labeling:

Safety Goggle
Model: EP05

Scan the QR code to find the instruction. For further issue, please contact the manufacturer: <http://it.cn/AGLgdy>

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

EC REP MedNet EC-REP GmbH (Medical)
Borkstrasse 10, 49163 Münster, Germany

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

Applied standards:
GB 14866-2006 / EN166:2001
ANSI/ISEA Z87.1-2015
Shelf life: 2 Years

Lot No.: AZ851
Production Date: August 2020

合格证 **受控**

本产品经检验合格，准予出厂！
产品品牌: Refine
产品名称: 医用防护目镜
产品成分: PVC 70% PC 30%
规格型号: EP05
包装规格: 1个/袋, 20个/盒, 10盒/箱
适用范围: 由高分子材料制成的防护面和固定装置组成，非灭菌提供，一次性使用。
执行标准: GB 14866-2006 / EN 166:2001
ANSI/ISEA Z87.1-2015
适用范围: 用于医疗环境中防止血液飞溅防护作用，能防化学、生物飞溅等。
生产数量: AZ851
生产日期: 2020年8月
有效期: 2年
检验日期: 2020年8月
生产许可证编号: 桂桂食药监械生产许20200014号
备案凭证/产品技术要求编号: 桂械备20200014号
生产企业: 桂林中远医疗器械有限公司
生产地址: 桂林中远医疗器械有限公司产业园3号D-08号地楼1#楼一层及2#楼、D-6地楼3楼1#楼南段及2、3、4楼; 贵州最大牙颌面修复老道村(地号:085A)1#厂房第一层

QC PASS

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-EP5-T001**

Test Reports: **C80602017**

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):

