REFINE

REFINE 1SN
EN166 3 S

Z87 D3

User's Manual of Face Shield

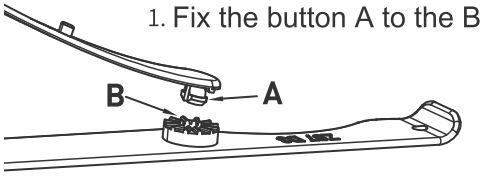
Face Shield is non-sterile disposable anti-fog Face Shield.

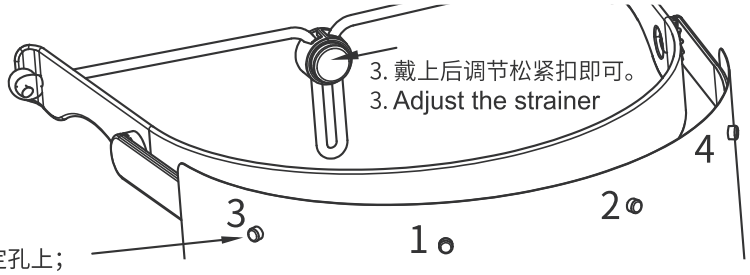
1. Brand: Refine
2. Product name: Face Shield
3. Material: Model A: PET 30% (Shield) PC 70% (Headwear),
   Model B: PET 80% PU sponge 20%.
4. Model: A, B (see packaging label for the detail model.)
5. Composition: composed of protective cover and fixing device made of polymer material. Non-sterile, single use.
6. Intended use : Face Shield is common eye protection equipment, which are used for protecting against droplets and splashes of liquids. Recommended industry: Facility Sanitation, Food Processing, Food Safety.
7. Product instruction: The product and the protective packaging should be checked before using. Stop using it if there is any damage.
8. 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.
9. 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.

Installation instructions (Model A)

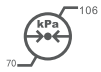
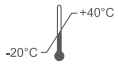
1. 将配件A前端收口，再挤压进B孔里，
   确保卡进去即可；
1. Fix the button A to the B hole.





2. 取出镜片将内外面的覆膜撕掉，再将镜片依次装在4个固定孔上；
2. Please remove the protective membrane on both sides of the shield, then fix the shield on the frame by buckling up 4 buttons IN ORDER.

Symbol instruction

Symbol 符号	Instruction 说明	
	Warning, Caution and Important ! Check the Instruction Manual	注意！查阅随机文件
	Date of manufacture	生产日期
	Recovery	可回收标志
	Keep dry	防潮标识
	Atmospheric pressure for storage	存贮条件，大气范围为70kPa～106kPa
	Temperature limitation for storage	存贮条件，温度范围为-20°C～+40°C
	Humidity limitation for storage	存贮条件，湿度范围为10%～93%
	Lot number	批次号
	EU Representative	欧盟授权代表
	Manufacturer	制造商
	Handle with care	易碎产品，小心轻放
	Consult the accompanying documents	查阅随机文件
	Single-Use	一次性使用
EAC	EAC certification	海关联盟（俄罗斯）认证
Z87 D3	According to ANSI/ISEA Z87.1-2015: D3-Special use，used to prevent Droplet / splash	根据美国ANSI/ISEA Z87.1-2015标准的分类： D3-特殊用途，用于防护液滴/飞溅
CE	CE certification 欧盟CE认证	MDEL MDEL certification 加拿大MDEL认证
REFINE 1SN EN166 3 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 3 - Field of use (Liquid Droplet/splash) S - Symbol for Increased robustness	根据欧盟EN 166:2001的防护分类： REFINE - 制造商商标 1 - 光学等级分类I类 S - 提高坚固性的符号（镜片） N - 防雾镜标识 EN 166 - 适用欧盟标准 3 - 防护液滴/飞溅 S - 提高坚固性的符号（镜架）

医用隔离面罩使用说明书

医用隔离面罩是非无菌一次性使用的防雾面罩。
1.品牌：Refine
2.产品名称：医用隔离面罩
3.产品成分：PET 30%(防护片) PC 70%(头架), Model B: PET 80% PU海绵 20%
4.产品型号：A，B
5.产品性能结构及组成：由高分子材料制成的防护罩和固定装置组成。非无菌提供，一次性使用。
6.适用范围：用于医疗机构中检查治疗时起防护作用，阻隔体液、血液飞溅或泼溅。
产品禁忌：暂不明确。
7.产品使用说明：本器械仅适用于其对应的适用范围，不应用于其他用途，用于其他用途将会损坏器械或者效果不好。应由专业人士进行操作使用，小心使用此器械。每次使用前，应对保护性包装和产品进行检查，如发现有破损的情况，该产品不应再继续使用。
注：产品生产日期参见产品包装标签。
8.注意事项
8.1 本器械为一次性使用产品，请勿重复使用；
8.2 器械使用时请严格遵守使用说明且在使用过程中不得经受冲击、摔打；
8.3 如发现器械有破损现象，请勿使用；
8.4 器械应避免与化学药品并放；
8.5 本产品不防高速颗粒冲击。
9.贮存
应贮存于清洁、干燥、通风，相对湿度为10%～93%，大气压力为70kPa～106kPa，温度为-20°C～+40°C的无腐蚀气体的室内环境中。
⚠警告
a. 与穿用者皮肤接触的材料可能对易过敏者造成过敏反应；
b. 产品有刮伤或损坏的，应予以更换；
c. 佩戴了普通标准眼镜后，再使用该产品，用于高速颗粒的防护时，可能会通过普通眼镜传递冲击力，从而对佩戴者造成危害。
d. 本产品适用于不存在光辐射危害的室内使用。

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

Shelf life: 2 Years

Product Standards 执行标准：GB 14866-2006 / EN 166:2001 / ANSI/ISEA Z87.1-2015 / AS/NZS 1337.1:2010

桂林市锐锋医疗 器械有限公司
产品名称：医用隔离面罩
生产备案凭证编号：桂桂食药监械生产备20170008号
备案凭证 / 产品技术要求编号：桂桂械备20200046号
备案人 / 生产企业/售后服务单位：桂林市锐锋医疗 器械有限公司
住所：桂林市七星区高新区信息产业园8-3号
生产地址：桂林市七星区高新区信息产业园8-3号；桂林市七星区高新区信息产业园D-08号地块
1#楼一层及2#楼　销售/售后服务电话/传真：0773-7796686　邮箱：sales1@refine-med.com
网址：http://www.refine-med.com　　使用年限：2年，其它内容参见说明书

EU DECLARATION OF CONFORMITY

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

Face Shield, A, Category II, AZ6A1

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):

A: 

Traceability Labeling:

Face Shield
Brand: Refine
Model: A
Lot No.: **AZ6A1**
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-MIA-T001**
Test Reports: C80202008R002

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-0002.**

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

EU DECLARATION OF CONFORMITY

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

Face Shield, B, Category II, AZ6B1

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):

B: 

Traceability Labeling:

Face Shield
Brand: Refine
Model: B
Lot No.: **AZ6B1**
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-MIB-T001**

Test Reports: C80282070

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