

# Medical Protective Goggles

Fighting COVID-19, We Are All Together



InnerMedical

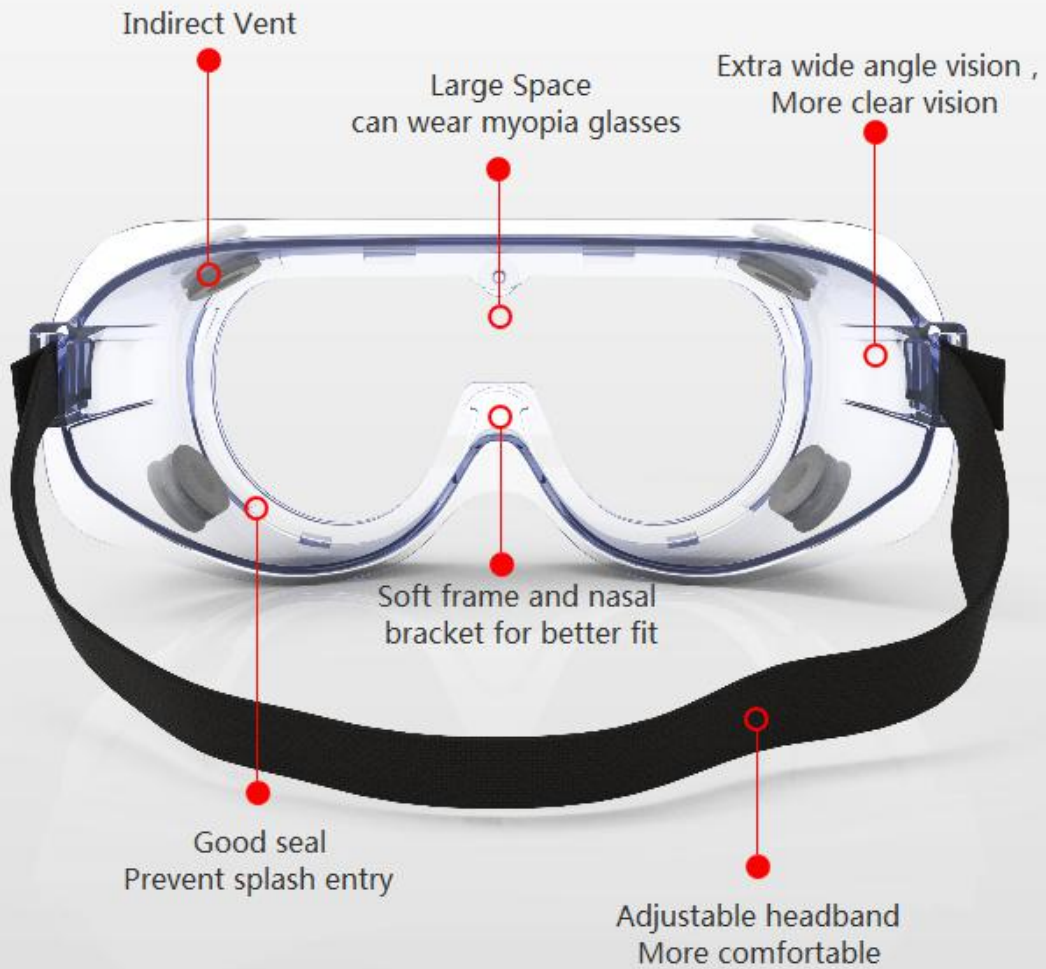


NMPA

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

# Medical Protective Goggles

## 2020AF



# Medical Protective Goggles

## Overall dimensions

The dimension of the goggles is shown in figure 1 (unit: mm). The tolerances should not exceed  $\pm 5\%$ .

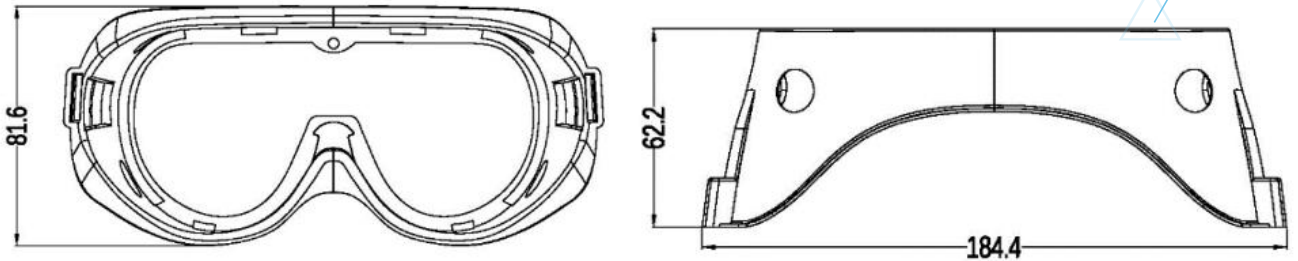


figure 1 Overall dimensions



**Medical Protective Goggles**

InnerMedical Co., Ltd.

N.G : 4 KG  
 Size : 51mm x 77mm x 220mm  
 Temperature : 20°C to 45°C  
 Relative humidity range : 45% to 95%  
 Atmospheric pressure : 1013hPa to 1040hPa  
 Be stored in dry conditions with no condensing exposure, out of any direct exposure to radiation

### Box size:

46cm×44cm×44cm

18.11inch×17.32inch×17.32inch

### Quantity:

100 PCS

### Weight:

9Kg

19.841b

### Volume weight

18kg

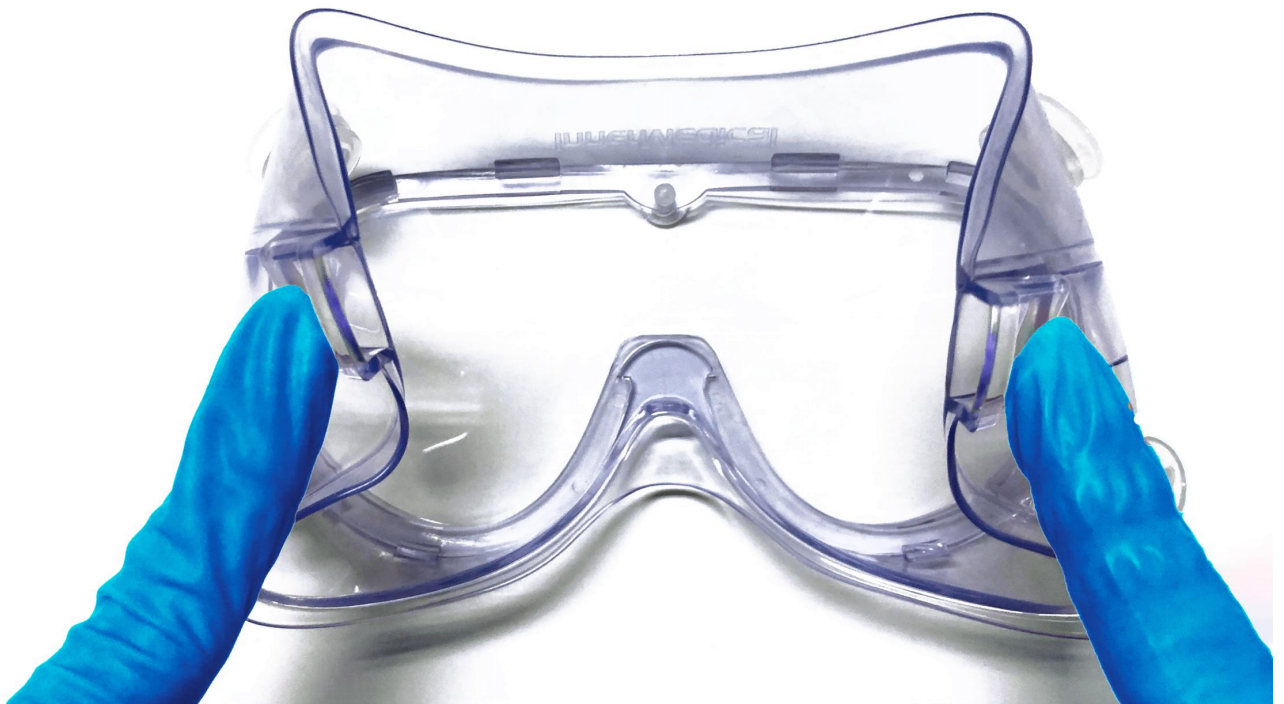
401b

# Medical Protective Goggles

**High resolution High transmittance Wide field**

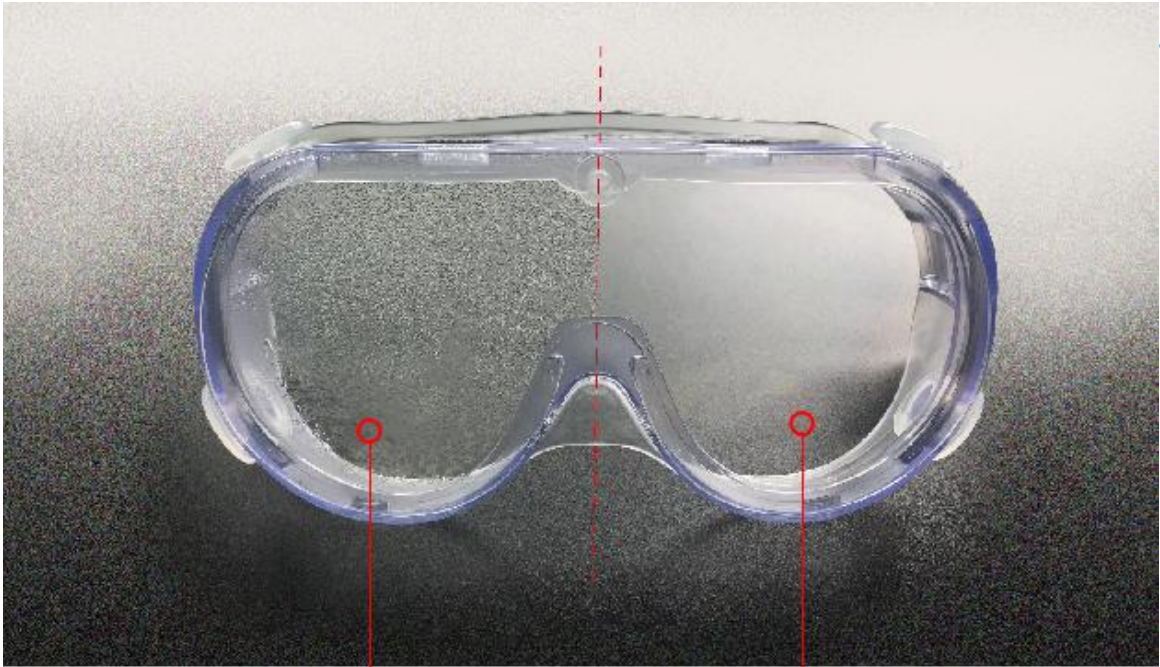


**Medical grade flexible PVC frame**





# Medical Protective Goggles



**Anti-fog coating**

**Uncoated**

**Ergonomics**



# Medical Protective Goggles

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## Product Component

Medical protective goggles are composed of lens, frame, bridge of nose decoration, vents and headband.

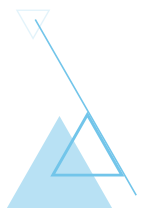
## Material

**Lens:** High transparent optical polycarbonate lens, provide impact resistance, protection against scratches, resistance to fogging, splash-proof. Small deviation of the depth of parallelism, no distortion.

**Frame:** Medical grade flexible PVC frame, soft and comfortable, suitable for various face shapes and good seal offers maximum protection.

The large space inside the frame, wide field of vision, can wear myopia glasses at the same time.

**Headband:** High elastic polybutadiene rubber headband, adjustable length, comfortable to wear, suitable for various head circumferences.



## 2020 Series

PN	Class
10.06.01.0011A	Economy
10.06.01.0009A	Business
10.06.01.0003A	Premium



### Specifications

<b>Case Quantity</b>	<b>100</b>
<b>Color Family</b>	<b>Transparent</b>
<b>Comfort Features</b>	<b>Adjustable elastic strap, Fits over most glasses, Indirect ventilation, Polycarbonate lens, Splash shield</b>
<b>Frame Color</b>	<b>Clear</b>
<b>Frame Style</b>	<b>Goggle</b>
<b>Lens Color</b>	<b>Clear</b>
<b>Lens Marking</b>	<b>Z87 D3</b>
<b>Lens Material</b>	<b>Polycarbonate</b>
<b>Product Color</b>	<b>Clear</b>
<b>Product Series</b>	<b>Splash</b>
<b>Product Type</b>	<b>Safety Goggle</b>
<b>Recommended Industry</b>	<b>Automotive, Chemicals, Food &amp; Beverage, General Manufacturing, Oil &amp; Gas, Pharmaceuticals</b>
<b>Splash Protection</b>	<b>Yes</b>
<b>Standards</b>	<b>ANSI/ISEA Z87.1-2015 / EN 166:2001</b>
<b>Strap Material</b>	<b>Cloth</b>
<b>Venting</b>	<b>Indirect</b>



Shenzhen Precision Eyewear  
Testing & Inspection Services Co., Ltd.



中国认可  
国际互认  
校准  
TESTING  
CNAS L2210

## Test Report

Report No.: PL 2003449 Page 1 of 8

**Applicant:** InnerMedical Co., Ltd.

**Address of Applicant:** 01 Area, 8/F, Block B, Haikexing Strategic Emerging Industrial Park, No. 16 Baoshan Road, Jinlong Avenue Intersection, Liulian Community, Pingshan Street, Pingshan District, Shenzhen, China

**Date of Receiving Samples:** Mar 24, 2020

**Testing Period:** Mar 25, 2020 to Mar 31, 2020

**Description of Samples**  
The submitted sample and sample information was/were submitted and identified by/on behalf of client:

**Sample Name:** Medical Protective Goggles  
**Model No.:** 2020AF  
**Device Type:** Goggles  
**Quantity:** 8 PCS  
**Material:** Plastic  
**Scale No.:** Clear  
**Lenses Type:** Clear, Plano  
**Frame Color:** Transparent & Black  
**Lenses Color:** Clear  
**Manufacturer/Brand:** Not provided  
**Buyer :** Not provided  
**Dimension:** Not provided  
**P/O. No.:** Not provided  
**Country of Origin:** Not provided  
**Country of Destination:** Not provided

**Tests Conducted:** As requested by the applicant, refer to attached page(s) for details.



To be continued

Date of Issue: Mar 31, 2020  
For and on behalf of:  
Shenzhen Precision Eyewear  
Testing & Inspection Services Co., Ltd.

*李华*

Manager: WenHua Li



Shenzhen Precision Eyewear  
Testing & Inspection Services Co., Ltd.



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## Test Report

Report No.: PL 2003449 Page 3 of 8

### Tests Conducted Summary

CLAUSES	REQUIREMENTS	RESULTS
5. General Requirements		
5.1 Optical Requirements		
5.1.1	Optical Quality	P
5.1.2	Luminous Transmission (Applicable for clear lenses)	P
5.1.3	Haze (Applicable for clear plano lenses)	P
5.1.4	Refractive Power, Astigmatism, Resolving Power, Prism and Prism Imbalance for Plano Protectors (Exempt from the requirement for the filter lenses of shade 9 or higher.)	P
5.2 Physical Requirements		
5.2.1	Drop Ball Impact Resistance (Protector first tested to and meeting the requirements of Section 6.2 are exempt from drop ball impact testing.)	P
5.2.2	Ignition (exclusive of textiles or elastic bands)	P
5.2.3	Corrosion Resistance of Metal Components	NA (No Metal Part)
5.2.4	Minimum Coverage Area	P
5.3	Markings	NR
5.4 Other Requirements		
5.4.1	Vented Goggles: The vented portion shall be such that the openings exclude spherical objects 1.5mm (0.06 in.) in diameter or greater and shall be no direct straight-line passage.	NA
5.4.4	Frames for Replaceable or Removable Lenses: Shall be supplied with detailed specifications on the required lens bevel design or mounting technique and nominal lens sizing	NA
5.5 Replaceable Lenses		
5.5.1	Goggles	Round lenses measuring 50 mm shall have a dimensional tolerance of $\pm 0.2$ mm.
		Rectangular lenses measuring 51 x 108 mm shall have a dimensional tolerance of $\pm 0.8$ mm.
5.5.2	Welding Helmets and Hand shields	NA

Remark: P = Pass; F = Fail; NA = Not Applicable, NR=Not Required; X=Checked;



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## Test Report

Report No.: PL 2003449 Page 2 of 8



### Conclusion:

**Tested Samples**  
Submitted Samples

### Standard

ANSI / ISEA Z87.1 - 2015 Occupation and Educational Personal Eye and Face Protection Devices, only test the related parameters of cover lenses, please refer to "Tests Conducted Summary" for details

### Result

Pass



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## Test Report

Report No.: PL 2003449 Page 4 of 8

### Tests Conducted

CLAUSES	REQUIREMENTS	RESULTS
6. Impact Protector Requirements		
6.1.1	Protectors Marked for Impact Rated Protectors: Impact-rated protectors and replaceable components shall meet the impact requirements and marking requirements in this standard.	NA (No Claimed)
6.1.2	Frames and Shells: Frames shall meet with high mass impact and high velocity impact (Exempt from the penetration requirement.)	NA (No Claimed)
6.1.3	Lateral (Side) Coverage	P
6.2 Impact Requirements		
6.2.2	High Mass Impact	NA
6.2.3	High Velocity Impact	NA
6.2.4	Penetration Test (lenses only)	NA
7. Optical Radiation Protector Requirements		
7.1	Protectors with Clear lenses	NA
7.2 Protector providing Filtrations of Optical Radiation		
7.2.1.2	Visible Light Filters (Refer to ANSI Z80.3-2010)	NA (Clear Lenses)
7.2.1.3	Variations in Luminous Transmittance	NA (Clear Lenses)
8.1	Droplet and Splash Hazard	P

Remark: P = Pass; F = Fail; NA = Not Applicable, NR=Not Required; X=Checked;





InnerMedical Co., Ltd. Version: 1.0

## Declaration of Conformity

**Manufacturer:** InnerMedical Co., Ltd.  
**Address:** 01 Area, 8/F, Block B, Haikexing Strategic Emerging Industrial Park, No. 16 Baoshan Road, Jinlong Avenue Intersection, Lulián Community, Pingshan Street, Pingshan District, Shenzhen, China  
**Product:** Medical Protective Goggles  
**Model:** 2020AF  
**Category:** Category I  
**Date CE mark affixed:** 2020

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

**Directives:** (EU) 2016/425 Personal Protective Equipment (PPE)  
**Standards:** EN 166: 2001 Personal eye - protection - Specifications

**Signature:**   
**Date:**  
**Name:** Kevin Zhang  
**Position:** Management Representative



Shenzhen Precision Eyewear Testing & Inspection Services Co., Ltd.



中国合格评定  
 国家认可  
 检测  
 TESTING  
 CNAS L2210

## Test Report

Report No.: PL2003010 Page 1 of 8

**Applicant:** InnerMedical Co., Ltd.  
**Address of Applicant:** 01 Area, 8/F, Block B, Haikexing Strategic Emerging Industrial Park, No. 16 Baoshan Road, Jinlong Avenue Intersection, Lulián Community, Pingshan Street, Pingshan District, Shenzhen, China

**Date of Receiving Samples:** Mar 02, 2020  
**Testing Period:** Mar 02, 2020 to Mar 06, 2020

**Description of Samples**  
 The submitted sample and sample information was/were submitted and identified by/on behalf of client;

**Sample Name:** Medical Protective Goggles  
**Model No.:** 2020AF  
**Quantity:** 9 Pairs  
**Material:** Plastic  
**Scale No.:** Not provided  
**Color:** Transparent / Black  
**P.O. No.:** Not provided  
**Supplier / Brand:** Not provided  
**Buyer:** Not provided  
**Goods exported to:** Not provided  
**Country of Origin:** China

**Requested Standard:**  
 EN 166: 2001 Personal eye - protection - Specifications;  
 EN 167: 2001 Personal eye - protection - Optical test methods;  
 EN 168: 2001 Personal eye - protection - Non-optical test methods;

**Results/Remarks:** Please refer to the following page(s).

Issued by stamp   
 Date of Issued: Mar 06, 2020  
 For and on behalf of:  
 Shenzhen Precision Eyewear Testing & Inspection Services Co., Ltd.  
 Manager: WenHua Li

4/F, Building A&B, No. 68 Xiaokang Road, Dakang Shangzhong Village, Henggang Town, Longgang District, Shenzhen, Guangdong, China  
 Tel: +86-0755-84264042 Fax: +86-0755-84263248 Email: info@pde-eyewear.com Website: www.pde-eyewear.com



Shenzhen Precision Eyewear Testing & Inspection Services Co., Ltd.



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## Test Report

Report No.: PL2003010 Page 2 of 8

### Tests Conducted

Note: The applicant's attention was drawn that the manufacturer should not use the frame materials which are known to cause irritation, allergic or toxic reaction during wear in a normal state of health against significant proportion of users.

Requirement	Testing				Results <sup>1</sup>		
	According to Clause		According to				
	EN	Clause	EN	Clause			
General construction	166	6.1	--	--	P		
Materials (Nickel release)	166	6.2	--	--	NA		
Headbands	166	6.3	--	--	NA		
Field of vision	166	7.1.1	168	18	P		
Refractive powers (Unmounted oculars covering one eye)	Spherical refractive powers		166	7.1.2.2.1	167	3.1	NA
	Astigmatic refractive powers						
	Prismatic refractive powers						
Refractive powers (Mounted oculars and covering both eyes)	Spherical refractive powers		166	7.1.2.1.2	167	3.2	Optical Class 2
	Astigmatic refractive powers						
	Prismatic refractive powers						
Transmittance	Oculars without filtering action		166	7.1.2.2.1	167	6	P
	Oculars with filtering action		166	7.1.2.2.2	167	6	NA
	Ultraviolet Filter		170	4	167	6	NA
	Sunglare Filter for Industrial Use		172	4.1	167	6	NA
Variations in transmittance (Exempt oculars without filtering action)	Oculars without corrective effect		166	7.1.2.2.3.1	167	7	NA
	Oculars with corrective effect		166	7.1.2.2.3.2	167	7	NA

4/F, Building A&B, No. 68 Xiaokang Road, Dakang Shangzhong Village, Henggang Town, Longgang District, Shenzhen, Guangdong, China  
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Shenzhen Precision Eyewear Testing & Inspection Services Co., Ltd.



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## Test Report

Report No.: PL2003010 Page 3 of 8

### Tests Conducted

Test Items	Requirement		Testing		Results		
	According to Clause		According to				
	EN	Clause	EN	Clause			
Diffusion of light	166	7.1.2.3	167	4	P		
Quality of material and surface	166	7.1.3	167	5	P		
Minimum robustness <sup>2</sup>	166	7.1.4.1	168	4	NA		
Increased robustness	Unmounted oculars		166	7.1.4.2.1	168	3.1	NA
	Complete eye-protectors and frame		166	7.1.4.2.2	168	3.2	P
Stability at an elevated temperature	166	7.1.5.1	168	5	P		
Resistance to ultraviolet radiation (oculars only)	166	7.1.5.2	168	6	P		
Resistance to corrosion (All metal parts only)	166	7.1.6	168	8	NA		
Resistance to ignition	166	7.1.7	168	7	P		
Protection against high-speed particles	166	7.2.2	168	9	NA		
Lateral protection	166	7.2.8	168	19	P		
Information supplied by the manufacturer	166	10	--	--	NR		

Remarks: 1. P = Pass; F = Fail; NA = Not Applicable; NR = Not require; X = Checked;  
 2. This requirement relates only to cover plates and oculars with filtering effect and not be assessed if these items are intended to meet the requirements for increased robustness or resistance to high speed particles, in which case the requirements of 7.1.4.2 or 7.2.2 shall be met.

4/F, Building A&B, No. 68 Xiaokang Road, Dakang Shangzhong Village, Henggang Town, Longgang District, Shenzhen, Guangdong, China  
 Tel: +86-0755-84264042 Fax: +86-0755-84263248 Email: info@pde-eyewear.com Website: www.pde-eyewear.com



深圳市精科眼镜检测检验服务有限公司

深圳市龙岗区横岗镇大康上中村小塘路 68 号 A、B 栋 4 楼  
电话: +86-0755-84264042 传真: +86-0755-84263248  
邮箱: info@jinko-optics.com 网站: www.jinko-optics.com

## 检验报告

No.: PL 2003011

第 1 页 共 8 页

产品名称	医用隔离眼罩	产品商标	未提供	规格型号	2020AF
产品类别	未明示	镜架材料	塑胶	颜色	无色透明
生产单位名称	深圳英美达医疗技术有限公司				
生产单位地址	深圳市坪山区坪山街道六联社区锦龙大道路口宝山路 16 号海科兴战略新兴产业园 B 栋 8 楼 01 区				
原产地	中国	销往区域	中国	生产日期或批号	2020 年 2 月
买家/客户	未提供				
样品到达日期	2020 年 03 月 02 日	样品数量	10 付	样品等级	合格
检测依据	GB 14866-2006 个人用防护用品技术要求				
检测日期	2020 年 03 月 02 日至 2020 年 03 月 05 日				
检测结论	送检样品检测项目符合标准要求。被判定合格。  签发日期: 2020 年 03 月 06 日				
备注	—				

经理批准: 李永平

审核: 李永平

主检: 李永平

## 医疗器械产品出口销售证明 CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号

Certificate No.: 粤深市监械出 2020Y032

产品名称: 医用隔离眼罩

Product(s): Medical Protective Goggles

规格型号: 2020、2020AF

Model: 2020、2020AF

产品注册或备案凭证号

Registration certificate(s): 粤深械备 20200068 号

生产企业: 深圳英美达医疗技术有限公司

Manufacturer: InnerMedical Co., Ltd.

生产企业住所: 深圳市坪山区坪山街道六联社区锦龙大道路口宝山路 16 号海科兴战略新兴产业园 B 栋 8 楼 01 区

Address of manufacturer: 01 Area, 8/F, Block B, Haikexing Strategic Emerging Industrial Park, No. 16 Baoshan Road, Jinlong Avenue Intersection, Liulian Community, Pingshan Street, Pingshan District, Shenzhen, China

生产许可或备案凭证号

Manufacturing License(s): 粤深食药监械生产备 20200019 号

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered to be manufactured and sold in China.

深圳市市场监督管理局  
Market Supervision Administration of  
Shenzhen Municipality

2020 年 / Year: 3 月 / Month: 16 日 / Day.

(此证明有效期与产品注册证有效期相同,且最长不超过两年)

(This certificate is valid for a period equal to the life of the product registration certificate and up to two years at a maximum)

## 第一类医疗器械备案信息表

备案号: 粤深械备 20200068 号

备案人名称	深圳英美达医疗技术有限公司
统一社会信用代码	91440300342615814B
备案人注册地址	深圳市坪山区坪山街道六联社区锦龙大道路口宝山路 16 号海科兴战略新兴产业园 B 栋 8 楼 01 区
生产地址	深圳市坪山区坪山街道六联社区锦龙大道路口宝山路 16 号海科兴战略新兴产业园 B 栋 8 楼 01 区
产品名称	医用隔离眼罩
型号/规格	2020、2020AF
产品描述	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。
预期用途	用于医疗机构中检查治疗时起防护作用,阻隔体液、血液飞溅或泼洒。
备注	无
备案单位和日期	深圳市市场监督管理局  备案日期: 2020-02-19
变更情况	

深圳市场局网站,可验证本证书。

方法 1: 详见市场局网站“药械信息查询栏目”;

<https://amr.sz.gov.cn/szyj/zwqk/search.jsp>

方法 2: 访问深圳市场局网站 <http://amr.sz.gov.cn>

点击首页的“-政务服务-信息查询-药械信息查询”,内有一类备案等市局证书的查询界面。

以上网页,推荐 IE8 及以上 IE 浏览器打开(IE10 以上请打开兼容视图模式)。

## 第一类医疗器械生产备案凭证

备案号: 粤深食药监械生产备 20200019 号

企业名称	深圳英美达医疗技术有限公司			
住所	深圳市坪山区坪山街道六联社区锦龙大道路口宝山路 16 号海科兴战略新兴产业园 B 栋 8 楼 01 区			
生产场所	深圳市坪山区坪山街道六联社区锦龙大道路口宝山路 16 号海科兴战略新兴产业园 B 栋 8 楼 01 区			
法定代表人	白晓松	企业负责人	白晓松	
生产范围	14-14 医护人员防护用品			
生产产品列表	产品名称	产品备案号	登记日期	备注
	医用隔离眼罩	粤深械备 20200068 号	20200219	-
	-	-	-	-
	-	-	-	-

备案部门: 

备案日期: 2020 年 02 月 24 日