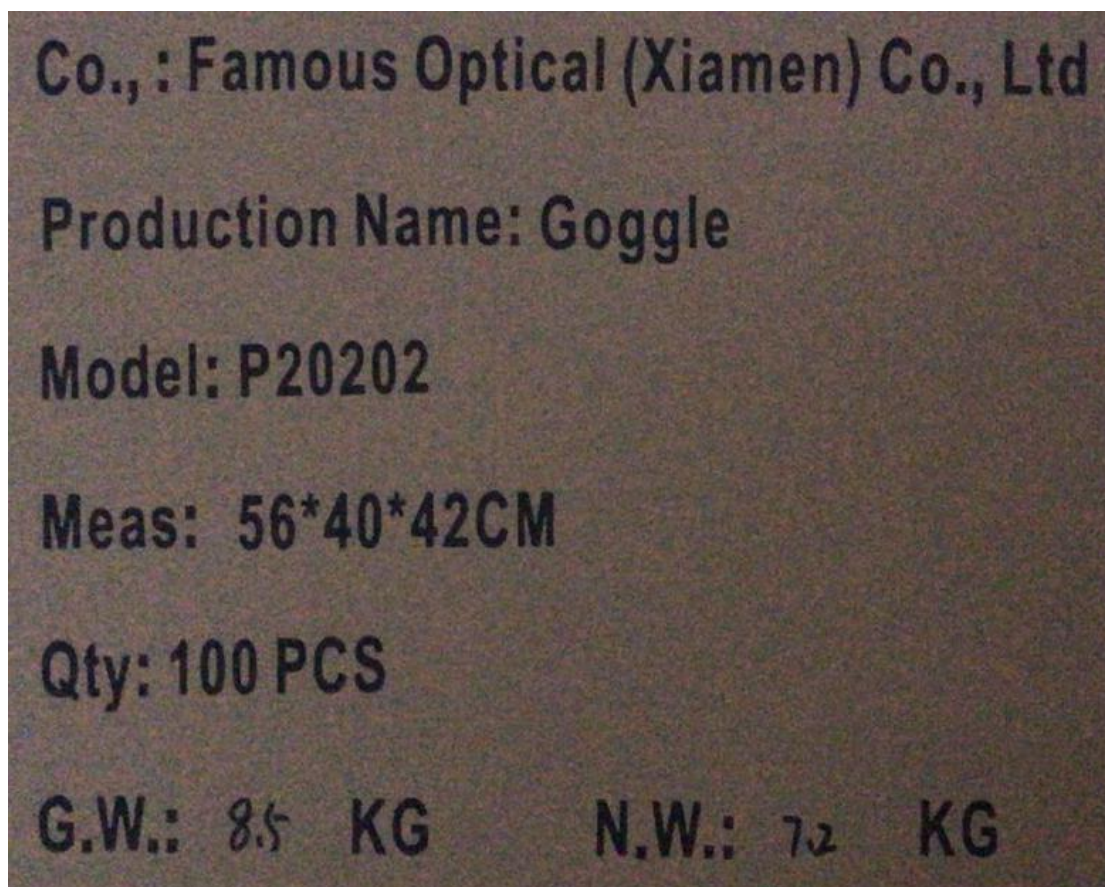


产品图片:



外包箱信息图片:



CE 认证:

شهادة - Certificate - 증명서 - 證明書 - Сертификат - Certificate - 證明書

Form QAT\_10-M04, version 00, effective since March 6th, 2020

## Certificate of Compliance



No. 2F200330B.FOX0093

Technical Construction File no. HCT02P202003027E

Certificate's Holder: Famous Optical (Xiamen) Co., Ltd  
Bldg 6, No. 599 Xinyongsheng Industry Park,  
Dianqian No.6 Road, Huli District, Xiamen, China

Certification ECM  
Mark:



Product: Personal Eye-Protection Goggles  
Model(s): P20202, P20203  
Verification to: Standard:  
EN 166:2001

related to CE Directive(s):  
R 2016/425 (Personal Protective Equipment)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: [www.entecerma.it](http://www.entecerma.it)

Issuance date: 30 March 2020

Expiry date: 29 March 2025

Reviewer  
Technical expert  
Amanda Payne



Approver  
ECM Service Director  
Luca Redonni



Ente Certificazione Macchine Srl

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☎ +39 051 6705141 📠 +39 051 6705156 ✉ [info@entecerma.it](mailto:info@entecerma.it) 🌐 [www.entecerma.it](http://www.entecerma.it)

# 护目镜（医用隔离眼罩）

营业执照：

	
<b>营 业 执 照</b>	
(副 本)	
统一社会信用代码 91350206612045613F	
名 称	扬名光学（厦门）有限公司
类 型	法人商事主体【有限责任公司（自然人投资或控股）】
注 所	厦门市湖里区殿前六路鑫永胜工业园B99之六（该住所仅限作为商事主体法律文书送达地址）
法定代表人	颜高祥
注 册 资 本	柒佰叁拾伍万捌仟壹佰陆拾元整
成 立 日 期	2002年03月19日
营 业 期 限	自2002年03月19日至2022年03月18日
经 营 范 围	商事主体的经营范围、经营场所、投资人信息、年报信息和监管信息等请至厦门市商事主体登记及信用信息公示平台（网址： <a href="http://www.xiamencredit.gov.cn">www.xiamencredit.gov.cn</a> ）查询。经营范围中涉及许可审批经营项目的，应在取得有关部门的许可后方可经营。
	
登 记 机 关	
2016 年 01 月 18 日	
企业信用信息公示系统网址： <a href="http://www.gsxt.gov.cn/">http://www.gsxt.gov.cn/</a>	
中华人民共和国国家工商行政管理总局监制	



第一类医疗器械备案凭证：

OPTICAL (XIAMEN)  
扬名光学  
(厦门)有限公司  
3780000420183

第一类医疗器械备案凭证

扬名光学（厦门）有限公司：

根据相关法规要求，对你单位第一类医疗器械：医用隔离眼罩予以备案，备案号：闽厦械备 20200049 号。

厦门市市场监督管理局  
日期：2020年2月17日

OPTICAL (XIAMEN)  
扬名光学  
(厦门)有限公司  
3780000420183

第一类医疗器械生产备案凭证

备案编号：闽厦食药监械生产备 20200009 号

企业名称	扬名光学（厦门）有限公司			
住所	厦门市湖里区殿前六路鑫永胜工业园 599 号之六			
生产地址	厦门市湖里区殿前六路鑫永胜工业园 599 之 6 第一二五层			
法定代表人	颜高祥	企业负责人	颜高祥	
生产范围	I 类：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	登载日期	备注
	医用隔离眼罩	闽厦械备 20200049 号	2020-02-17	
	***			

备案部门（公章）：厦门市市场监督管理局  
备案日期：二〇二〇年二月十七日

检测报告：

MA

151300110136

检测报告

TEST REPORT

No. 2020C-W0048

样品名称

护目镜（医用隔离眼罩）

Name of Sample

型号规格

P20202

Type & Specification

送检单位

扬名光学（厦门）有限公司

Client

厦门市产品质量监督检验院

XIAMEN PRODUCTS QUALITY SUPERVISION & INSPECTION INSTITUTE

厦门市产品质量监督检验院

检测报告

No.2020C-W0048

第 1 页 共 3 页

产品名称	护目镜（医用隔离眼罩）	型号规格	P20202
检验类别	委托检测	商 标	/
标称生产单位	扬名光学（厦门）有限公司	生产日期	/
样品来源	送检单位	扬名光学（厦门）有限公司	批（编）号
	联系人/送样人	张婷艺	样品等级
	联系地址	湖里区殿前六路鑫永胜工业园599之六	样品数量
	联系电话	13950102802	送样日期
	邮政编码	/	报告日期
样品状态	试验前样品外观正常，符合试验要求。		
检测依据	GB 14866-2006 个人用眼防护用品技术要求		
检测项目	见续页		
检测时间	2020-02-17 ~ 2020-02-18		
检测说明	/		
主送单位	扬名光学（厦门）有限公司	实验地点	院本部实验室
批准：	张婷艺	审核：刘雪云	主检：许世敏

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厦门市产品质量监督检验院  
检测报告

编号: 2020C-W0048  
第 2 页 共 3 页

(续页)

序号	标准条款	检测项目	标准要求	检测结果	单项判定
1	GB 14866 5.2	结构	表面光滑、无毛刺、无锐角或可能引起眼部不适感的其他缺陷;应具有良好的透气性;可调零件或结构部件应易于调节和替换。	全部通过	符合
2	GB 14866 5.3	头箍	在与佩戴者接触的任一部位头箍宽度至少应保持 10mm,头箍应能调节,选用材料应质地柔软,经久耐用。	在与佩戴者接触的任一部位头箍宽度均大于 10mm,头箍均能调节,选用材料均质地柔软,经久耐用。	符合
3	GB 14866 5.4	镜片规格 mm	单镜片:长×宽尺寸不小于 105mm×50mm。 双镜片:成型镜片的水平基准长度×垂直高度不小于 30mm×25mm。	长: 146.0 宽: 70.8 /	符合
4	GB 14866 5.5	镜片的外观质量	镜片表面应光滑、无划痕、波纹、气泡、杂质或其他可能有损视力的明显缺陷。	全部通过	符合
5	GB 14866 5.6	屈光度互差 (D)	-0.07~+0.05	-0.03~0.00	符合
		棱镜度互差 (Δ)	≤0.125	0.00~0.07	符合
		左右眼镜片棱镜度互差 (Δ)	≤0.18	均为 0.00	符合
		可见光透射比 %	无色透明镜片: >89	左眼: 89.7 右眼: 89.7	符合
6	GB 14866 5.7	抗冲击性能	经抗冲击试验后,不应发生下列缺陷:镜片破损,镜片变形,眼护具框架破损。	全部通过	符合

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厦门市产品质量监督检验院  
检测报告

编号: 2020C-W0048  
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(续页)

序号	标准条款	检测项目	标准要求	检测结果	单项判定
7	GB 14866 5.8	耐热性能	经耐热性能试验后,应无异常现象出现。镜片的光学性能在 5.6 规定的范围内无变化。	全部通过	符合
8	GB 14866 5.9	耐腐蚀性能 (适用于有金属部件的眼护具)	经耐腐蚀试验后,眼护具的所有金属部件应呈无氧化的光滑表面。	无金属部件	/
9	GB 14866 5.10	有机镜片的表面耐磨性能 (适用于有机材料制成的眼护具)	经耐磨性试验后,镜片表面磨损率应低于 8%。	镜片表面磨损率: 3.3%	符合
10	GB 14866 5.11	防高速粒子冲击性能 (适用于防护高速粒子冲击的眼护具)	经高速粒子 (45m/s) 冲击后,不应发生下列缺陷:镜片破损,镜片变形,眼护具框架破损,侧面防护失效。	非防护高速粒子冲击眼护具	/

注:“/”表示该项目不适用。

样品照片:



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### Test Report

Report No.: PL2003595

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Applicant: Famous Optical (Xiamen) CO., LTD

Address of Applicant: Bldg 6, No.599 Xinyongsheng Industry Park, Dianqian No.6 Road,  
Hui District, Xiamen, Fujian, CHINA

Date of Receiving Samples: Mar 31, 2020

Testing Period: Mar 31, 2020 to Apr 03, 2020

#### Description of Samples

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

Sample Name: Personal Eye-Protection Goggles  
Model No.: P20202  
Quantity: 11 Pairs  
Material: Plastic  
Scale No.: Not provided  
Color: Clear /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: Apr 03, 2020

For and on behalf of:

Shenzhen Precision Eyewear

Testing & Inspection Services Co., Ltd.

Manager: WenHua Li



### Test Report

Report No.: PL2003595

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#### 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>
Test Items		According to Clause		According to	
		EN	Clause	EN	Clause
General construction		166	6.1	--	--
Materials (Nickel release)		166	6.2	--	--
Headbands		166	6.3	--	--
Field of vision		166	7.1.1	168	18
Refractive powers (Unmounted oculars covering one eye)	Spherical refractive powers	166	7.1.2.1.1	167	3.1
	Asigmatic 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
	Asigmatic refractive powers				
	Prismatic refractive powers				
Transmittance	Oculars without filtering action	166	7.1.2.2.1	167	6
	Oculars with filtering action	166	7.1.2.2.2	167	6
	Ultraviolet Filter	170	4	167	6
	Sunglare Filter for Industrial Use	172	4.1	167	6
Variations in transmittance (Exempt oculars without filtering action)	Oculars without corrective effect	166	7.1.2.2.3.1	167	7
	Oculars with corrective effect	166	7.1.2.2.3.2	167	7





**Test Report**

Report No.: PL2003595

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**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	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.



**Test Report**

Report No.: PL2003595

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**Test Result**

**General construction — Clause 6.1**

Sample No.	General construction		Headbands				Comment	Result(s)
	Defects		Width		Adjustable			
	Observed	Absent	Pass	Fail	Yes	No		
2003595-(01-03)		X	X		X		—	P
Requirements:								
1. General construction: Eye-Protectors shall be free of projections, sharp edges or other defects which are likely to cause discomfort or injury during use.								
2. Headbands: shall be at least 10mm wide over any portion which may come into contact with the wearer's head and shall be adjustable or self-adjusting.								

**Field of vision — Clause 7.1.1 / EN 168:2001 Clause 18**

Sample No.	Head-form		Exhibit minimum field of vision defined in the standard		Comment	Result(s)
	Medium	Small	Yes	No		
2003595-(01-03)	X		X		—	P
Requirements:						
Eye-Protectors shall be exhibit field of vision an area of not less than 22 mm in the horizontal length and 20mm in the vertical width in front of each eye.						

**Refractive powers— Clause 7.1.2.1.2 / EN 167:2001 Clause 3.2**

Sample No.	Refractive powers				Difference in prismatic refractive powers (cm/m)			Result(s)
	Spherical (m <sup>-1</sup> )		Astigmatic (m <sup>-1</sup> )		Horizontal		Vertical	
	Left	Right	Left	Right	Base Out	Base In		
2003595-01	+0.01	+0.01	0.00	0.00	0.03	--	0.00	Optical class 1
2003595-02	+0.01	0.00	0.00	0.00	0.03	--	0.01	
2003595-03	+0.01	+0.01	0.00	0.00	0.02	--	0.02	
Requirement: Permissible tolerances for refractive powers :								
Optical class 1	±0.06		0.06		0.75	0.25	0.25	
Optical class 2	±0.12		0.12		1.00	0.25	0.25	
Optical class 3	+0.12~ -0.25		0.25		1.00	0.25	0.25	

Measurement Uncertainty (if necessary):





### Test Report

Report No.: PL2003595

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#### Test Result

Transmittance (without filtering action) — Clause 7.1.2.2 / EN 167:2001 Clause 6

Sample No.	Requirements	Luminous Transmittance, $T_v$ (%)		Result(s)
		Left	Right	
2003595-01	$T_v > 74.4\%$	90.2	90.0	P
2003595-02		90.4	90.7	P
2003595-03		90.6	90.7	P

Measurement Uncertainty (if necessary):

Diffusion of light — Clause 7.1.2.3 / EN 167:2001 Clause 4

Sample No.	Samples type	Diffusion of light (cd/m <sup>2</sup> ) / lx		Result(s)
		Left	Right	
2003595-01	III	0.04	0.03	P
2003595-02		0.05	0.06	P
2003595-03		0.07	0.04	P

Requirements:  
The maximum value of the reduced luminance factor shall be :  
I 1.00 (cd/m<sup>2</sup>) / lx for welding filter;  
II 0.75 (cd/m<sup>2</sup>) / lx for oculars used in eye-protectors against high speed particles;  
III 0.50 (cd/m<sup>2</sup>) / lx for all other oculars;

Measurement Uncertainty (if necessary):



### Test Report

Report No.: PL2003595

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#### Test Result

Quality of material and surface — Clause 7.1.3 / EN 167:2001 Clause 5

Sample No.	Defects		Comment	Result(s)
	Observed	Absent		
2003595-(01-03)		X	--	P

Requirements:  
Except in a marginal area 5 mm wide, oculars shall be free from any significant defects likely to impair vision in use, such as bubbles, scratches, inclusions, dull spots, pitting, mould marks, scouring, grains, pocking, scaling and undulation.

Increased robustness — Clause 7.1.4.2 / EN 168:2001 Clause 3.1

Sample No.	Test temperature (°C)	Test position	Defects		Comment	Result(s)
			Observed	Absent		
2003595-(04-05)	55	Left Frontal		X	--	P
2003595-06		Left Lateral		X	--	P
2003595-(07-08)	-5	Left Frontal		X	--	P
2003595-09		Left Lateral		X	--	P
2003595-(04-05)	55	Right Frontal		X	--	P
2003595-06		Right Lateral		X	--	P
2003595-(07-08)	-5	Right Frontal		X	--	P
2003595-09		Right Lateral		X	--	P

Requirements:  
The following defects shall not occur:  
1. ocular fracture;  
2. Ocular deformation;

Stability at an elevated temperature — Clause 7.1.5.1 / EN 168:2001 Clause 5

Sample No.	Apparent deformation		Comment	Result(s)
	Observed	Absent		
2003595-(04-06)		X	--	P

Requirements:  
Assembled eye-protectors shall show no apparent deformation;



## Test Report

Report No.: PL2003595

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### Test Results

Resistance to ultraviolet radiation (oculars only) — Clause 7.1.5.2 / EN 168:2001 Clause 6

Samples type		Sample No.					
Other oculars		2003595-01		2003595-02		2003595-03	
Test Items		Left	Right	Left	Right	Left	Right
The relative change of luminous transmittance (%)	Before Expose	90.2	90.0	90.4	90.7	90.6	90.7
	After Expose	90.0	90.1	90.7	89.9	90.1	90.0
	Difference	-0.2	0.1	0.3	-0.9	-0.6	-0.8
Reduced scattered light coefficient (cd/m <sup>2</sup> ) / lx	Before Expose	0.04	0.03	0.05	0.06	0.07	0.04
	After Expose	0.05	0.06	0.06	0.06	0.10	0.07
Result(s)		P		P		P	
Requirements:							
1. The relative change of luminous transmittance				2. Reduced scattered light coefficient			
Luminous transmittance		Permissible relative Change (%)		The maximum value of the reduced luminance factor shall be:			
Less than (%)	Up to (%)			- 1.00(cd/m <sup>2</sup> ) / lx for welding filter;			
100	17.8	±5		- 0.75(cd/m <sup>2</sup> ) / lx for oculars used in eye-protectors against high speed particles;			
17.8	0.44	±10		- 0.50 (cd/m <sup>2</sup> ) / lx for all other oculars;			

Measurement Uncertainty (if necessary):

Resistance to ignition — Clause 7.1.7 / EN 168:2001 Clause 7

Sample No.	Continued combustion		Comment	Result(s)
	Yes	No		
2003595-(04-06)		X	—	P
Requirements: Eye-protectors shall be considered to be satisfactory if no parts ignites or continues to glow after removal of the steel rod.				



## Test Report

Report No.: PL2003595


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### Test Results

Lateral Protection — Clause 7.2.8 / EN 168:2001 Clause 19

Sample No.	Lateral region coverage		Comment	Result(s)
	Pass	Fail		
2003595-(01-03)	X		--	P
Requirements: Eye-protectors claimed to lateral protection shall pass the lateral region coverage. These region being a 20mm wide with 10 mm radial ends struck from the front and side impact points (See figure 1)				

**Figure 1:**



Sample Photo:



---Report End---

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