

# 医用隔离面罩/面屏全套资料文件

## 一、Product characteristics——advantage

### 一、产品特点——优势：

1、采用进口 PET 膜片，透明度高、耐酸碱、抗划痕

1.Imported PET film, high transparency, acid and alkali resistance, scratch resistance

2、重复使用（当天使用完酒精擦拭可再次使用）

2. Reuse (can be used again when the angel uses up alcohol to wipe)

3、高度防雾功能

3. High anti fog function

4、可直接覆盖近视眼镜

4. It can cover myopia glasses directly

5、使用各种头型

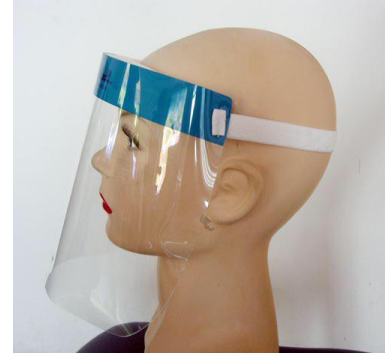
5. Use a variety of head styles

6、公司获得 CE 认证，产品获得欧盟检测报告，产品质量可靠

6. The company has obtained CE certification, the product has obtained EU test report, and the product quality is reliable

7、产品获得中国第一类医疗器械备案凭证，证件齐全；

7.The product has obtained the first class medical device record certificate in China, with complete certificates



### 二、产品使用领域：

#### 二、Product use area:

1、医用和其他卫生科研机构；

1. Medical and other health research institutions;

2、医药、食品、化妆品行业；

2. Pharmaceutical, food and cosmetics industries;

3、家用、办公用

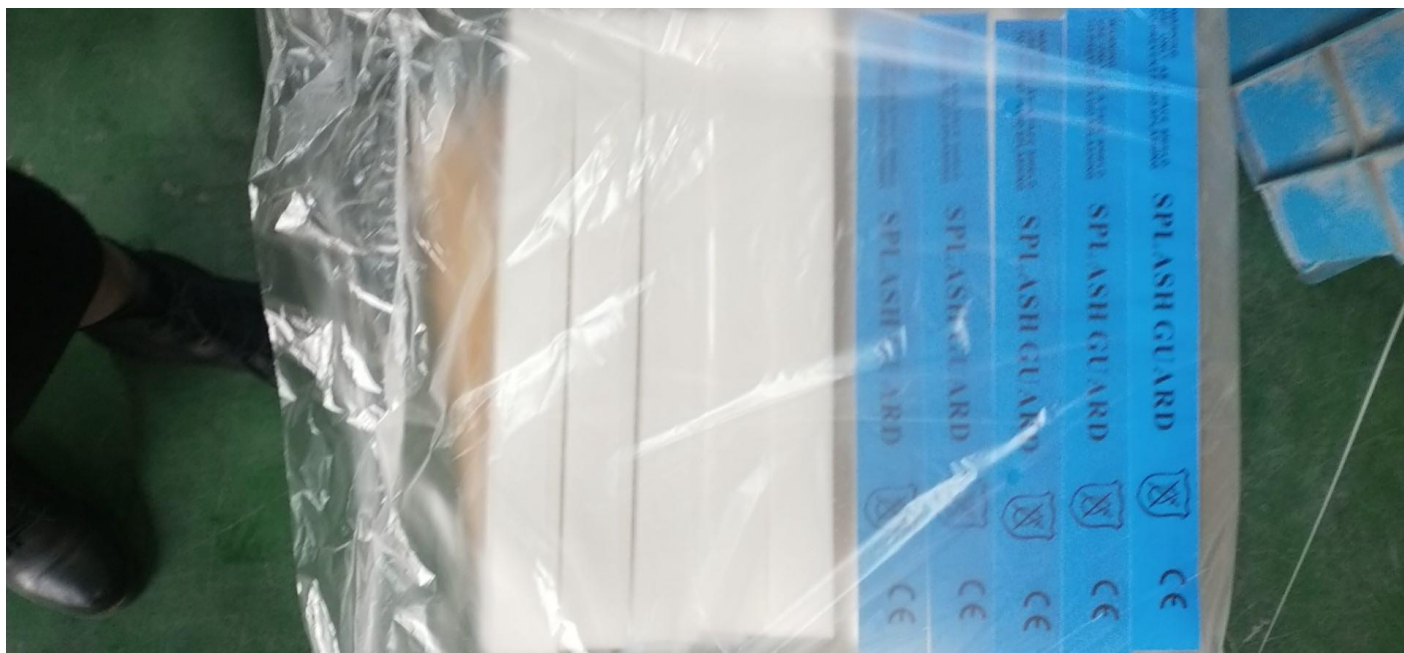
3. For home and office use

-----使用真实图片/Use real pictures -----



型号/Model: MZ-5

### 三、内部装箱(尺寸、重量、每天产能)



医用隔离面罩（面屏）：每箱 200 个；

装箱信息：体积 0.09 立方，重量 6.5 千克，纸箱尺寸：66cm\*37cm\*37cm；

每天产量：每天生产 3 万-10 万个（具体根据下单的量来约定）；





五、生产车间真实图片





## EU type-examination certificate

CE 认证编号

C9106.3HKH

Applicant / manufacturer

Kanghua Safety Equipment  
Manufacturing Co., Ltd.  
Dianhouzhou Village  
Zhuge Town  
LANXI CITY  
ZHEJIANG PROVINCE  
P.R. CHINA

**Kanghua Safety Equipment Manufacturing Co., Ltd.**

Identification of the manufacturer

HKH

Product type

Face-shield, visor for medical appliances

满足欧盟标准

Model names

MZ-5

Standard(s) /  
technical rules

Essential requirements according to  
Annex II of the PPE-Regulation (EU) 2016/425  
EN 166 : 2001 (partially applied)

Test report(s)

10743-ECS-09,  
1143-ECS-16 / MR 11433-ECS-16

Material and  
optical properties

Safety plates: plastics  
Luminous transmittance NA 89%  
Protection against liquid splashes

Marking

HKH 1 3 CE  
NOT SUITABLE TO PROTECTING AGAINST  
ANY MECHANICAL IMPACT!

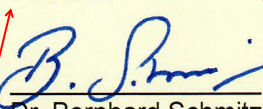
Herewith, ECS certifies that the named model complies with the essential requirements for health and safety as they are provided by the European Regulation (EU) 2016/425 for Personal Protective Equipment. This certificate is based both / either on the test results as they are summarized in the named test reports, and/or on the technical documentation as it is delivered by the manufacturer. The applicant / manufacturer agrees to the General Business Rules of the ECS GmbH and to additional agreements as they are named in the application for conformity assessment.

The eye-protection device is to be marked as assigned. Either / both the frame and/or the ocular, spectacle, goggle or shield must be signed, as appropriate. If different markings have been assessed, the lowest marking must be applied, respectively. The validity of this EU type-examination certificate will expire on the date as mentioned below, and/or if the manufacturer modifies the safety-relevant properties of this product with comparison to the tested one and/or if the requirements in the standards or technical rules will be revised and/or tightened.

Name, address and identification number 1883 of the notified body ECS are to be indicated in the information brochure of this product.

**This EU type-examination certificate is valid until 2021-06.**

ECS GmbH  
Notified Body 1883  
11/04/19

  
Dr. Bernhard Schmitz  
ECS-Certification



ECS GmbH – European Certification Service  
Augenschutz und Persönliche Schutzausrüstung  
Laserschutz und Optische Messtechnik  
Hüttfeldstraße 50  
73430 Aalen, Germany

发证日期

## 外包装箱子图片

### 四、生产单位资质

#### 1、公司资质





营业执照

第一类医疗器械生产备案凭证

备案编号：浙金食药监械生产备20200006号

企业名称	兰溪市康华防护用品有限公司		
住所	浙江省金华市兰溪市诸葛镇工业功能区B区		
生产场所	浙江省金华市兰溪市诸葛镇工业功能区B区		
法定代表人	余夏雨	企业负责人	余夏雨
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	备注
	医用隔离面罩	浙金械备20200013	(防控新型冠状病毒感染的肺炎疫情应急备案,有效期6个月)
	医用隔离眼罩	浙金械备20200014	(防控新型冠状病毒感染的肺炎疫情应急备案,有效期6个月)
	***		

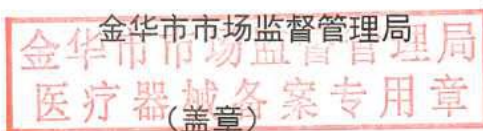
金华市市场监督管理局  
医疗器械备案专用章(兰溪)

一类生产备案（相当于生产许可证）

## 第一类医疗器械备案凭证

兰溪市康华防护用品有限公司

根据相关法规要求，对你单位第一类医疗器械：医用隔离面罩予以备案，备案号：浙金械备20200013号。（防控新型冠状病毒感染的肺炎疫情应急备案，有效期6个月）



日期：2020年02月12日

# 第一类医疗器械备案信息表

备案号：浙金械备20200013号

备案人名称：	兰溪市康华防护用品有限公司
备案人组织机构代码：	91330781MA29RU7X2R
备案人注册地址：	浙江省金华市兰溪市诸葛镇工业功能区B区
生产地址：	金华市兰溪市诸葛镇殿后朱工业区
代理人：	/
代理人注册地址：	/
产品名称：	医用隔离面罩
型号/规格：	MZ-5 均码
产品描述：	通常由高分子材料制成的防护罩、泡沫条和固定装置组成。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、血液飞溅和泼溅。
备注：	
备案单位和日期：	<div> <div>金华市市场监督管理局</div> <div>医疗器械备案专用章</div> <div>备案日期：2020年02月12日</div> </div>
变更情况：	



## 2、产品资质-医用隔离面罩（面屏）的检测报告——欧盟检测报告



Test report 1074-ECS-09 from 12/10/2009	Measurement report 3: page 1 of 5
Test mark:	10743-ECS-09
Type:	MZ-5 Face shield / thin clear visor for medical , biochemical and / or pharmaceutical applications

### Measurement report 3

#### Description of the type

Design:

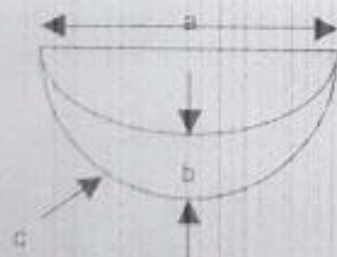


Visor made of a clear plastic foil, less than 200  $\mu\text{m}$  thick, only suitable for medical, biochemical and/or pharmaceutical use. It can be only applied in situations where no need to protect against mechanical impacts exists.

Visor thickness / mm: middle: 1.00 – 0.05 mm

Vertex power:  
horizontal / vertical / dpt: 0

Dimensions:  
thickness / mm 0.15  $\pm$  0.01  
a / mm: 1  
b / mm: 220 / height of viewing area / mm: 184  
c / mm: 332



Frame:	Identification mark	Medi-Select LTEE FOURNITURES & ÉQUIPEMENTS MÉDICAUX PRODUITS PHARMACEUTIQUES
	Material	Plastics, foam plastics, elastic headband made of ribbon

Test mark:	10743-ECS-09
Type:	MZ-5 Face shield / thin clear visor for medical, biochemical and / or pharmaceutical applications

Filter:	identification mark:	none
	material:	plastics very thin, not suitable to protect against any mechanical impact
Additional information delivered by the manufacturer: None		

**Quality of material and surface, diffusion of light, refractive powers, transmittance**

test ↓                      sample →		9074					
		-46	-47	-48	-49	-50	-51
quality of material and surface		+	+	+	-	+	+
field of vision		+	+	+	-	+	+
area of coverage, side protection		+	+	+	-	+	+
spherical refractive power	dpt	0	-0.01	0	-0.01	-0.01	0
astigmatic refractive power	dpt	0.01	0.01	0.01	0.01	0.01	0.01
prismatic power (horizontal / vertical)	cm/m	BO 0.05 / 0	BO 0.1 / 0	BO 0.15 / 0	BO 0.05 / 0	BO 0.1 / 0	BO 0.1 / 0
reduced luminance coefficient, diffusion of light	cd/m <sup>2</sup> lx	0.37	0.35	0.33	0.45	0.36	0.34
optical class		1	1	1	1	1	1
luminous transmittance rel NA r	%	89.0	89.6	89.5	88.7	89.4	89.2
luminous transmittance rel D65 r	%	89.0	89.8	89.5	88.7	89.4	89.4



Test mark:	10743-ECS-09
Type:	MZ-5 Face shield / thin clear visor for medical , biochemical adn / or pharmaceutical applications

**Quality of material and surface, diffusion light, refractive powers, transmittance after test to thermal ageing**

test ↓                      sample →		9074		
		-46	-47	-48
quality of material and surface		without any visible alterations after thermal ageing		
spherical refractive power	dpt	0.01	0.01	0
astigmatic refractive power	dpt	0	0	0
reduced luminance coefficient, diffusion of light	$\frac{\text{cd/m}^2}{\text{lx}}$	0.44	0.43	0.41
luminous transmittance rel NA ±	%	89.0	89.3	89.4
relative change of transmittance	%	0	0	0

**Quality of material and surface, diffusion light, refractive powers, transmittance after test to UV ageing**

test ↓                      sample →		9074		
		-49	-50	-51
quality of material and surface		without any alterations after UV ageing		
spherical refractive power	dpt	0	0	0.01
astigmatic refractive power	dpt	0	0.01	0
reduced luminance coefficient, diffusion of light	$\frac{\text{cd/m}^2}{\text{lx}}$	0.38	0.33	0.45
luminous transmittance rel NA ±	%	87.3	87.6	88.6
relative change of transmittance	%	1.6	2.0	0.7

Test mark:	10743-ECS-09
Type:	MZ-5 Face shield / thin clear visor for medical, biochemical and / or pharmaceutical applications

#### Increased robustness

sample →	test →	Test temperature / °C	Test point	Results
9074-52		-5	frontal, left side	+
9074-53		-5	frontal, left side	+
9074-54		-5	frontal, right side	+
9074-55		-5	frontal, right side	+
9074-56		-5	left side	+
9074-57		-5	right side	+
9074-58		+55	frontal, left side	+
9074-59		+55	frontal, left side	+
9074-60		+55	frontal, right side	+
9074-61		+55	frontal, right side	+
9074-62		+55	left side	+
9074-63		+55	right side	+

**General remark:** The safety plates / visors are very thin, less than 0.2 mm. Even if no damage or hurt on the eyeballs has been observed, when the test on Increased Robustness has been done, the ECS test house recommends to use these visors only in situations, e.g. in a medical, clinical, biochemical or pharmaceutical environments where it is unlikely that any mechanical impact occurs. For those applications, the visor shall be marked by: **NOT SUITABLE TO PROTECTING AGAINST ANY MECHANICAL IMPACT!**



Test mark:	10743-ECS-09
Type:	MZ-5 Face shield / thin clear visor for medical, biochemical and / or pharmaceutical applications

### Inflammability / Resistance to ignition

test ↓	sample →		9074	
		55	56	57

inflammability, resistance to ignition    Temperature > 650°C  
 headband, foam material and lenses / visors  
 no ignition, no further glowing

### Protection against droplets and splashes of liquids for visors and face-shields

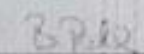
test ↓	sample →		9074	
		52	53	54
height	mm	>150	>150	>150
protection		-	+	+

### Resistance to fogging

test ↓	sample →		9074	
		64	65	66
			66	67

Test samples remain free from fogging for                      less than 1 sec, no antifog properties

Aalen (Germany), 12. Oct. 2009

  
 Dipl.-Ing. Bastian Pedal  
 ECS test engineer

## 六、医用隔离面罩（面屏）英文使用说明书

### USER INSTRUCTIONS

MZ-5 Face-shield, visor for medical appliances

#### User instruction

#### Description

These eye-protectors are face-shield, visor for medical appliances with plastics lens.

#### Field of Use (Protection capabilities and performance characteristics)

These products are intended for protection against liquid splashes, as encountered in medical activities, etc. which are likely to damage the eye or impair vision.

#### Service life

The visor should be replaced after three years in service.

#### Storage and Maintenance

If possible, store the product in a container when not using it.

Cleaning is recommended after each use. The product should be cleaned using a cloth moistened with warm soapy water and dried at room temperature. A suitable lens cleaning cloth may also be used.

Do not use petrol, chlorinated degreasing fluids, organic solvents or abrasive cleaning agents to clean any part of the equipment.

The product can be disinfected with alcohol or disinfectant fluid regularly.

#### Accessories and spare parts

Accessories: protective covers to the lens, user manual

There is no spare parts.

#### Standards and Approval

The Face Shield System are classed as Personal Protective Equipment (PPE) by the European PPE new regulation (EU) 2016/425 and have been shown to comply with this regulation through the Harmonized European Standard EN1731:2006: Mesh eye and face protectors

#### Marking

HKH 1 3 CE

Manufacturer's code: HKH

Optical class: 1

Protection against liquid splashes : 3

#### Use Limitation and warning

- 1.This visor is not suitable to protect against any mechanical impact.
- 2.Never modify or alter this product.
- 3.Do not use this product against hazards other than those specified in this document/product user instructions.
- 4.Scratched or damaged oculars should be replaced.
- 5.Materials which may come into contact with the wearer's skin could cause allergic reactions to



susceptible individuals.

6.The compatibility of the marking shall be ensured, or the protection afforded by the goggles may be impaired.

**Manufacturer information**

KANGHUA SAFETY EQUIPMENT MANUFACTURING CO.,LTD  
Dianhouzhou Village, Zhuge Town, Lanxi City,  
Zhejiang, China

**Declaration of conformity**

Hereby,KANGHUA declares that face shields MZ-5 are in compliance with Regulation (EU) 2016/425 The full text of the EU declaration of conformity is available at the following internet address: [WWW.PPESAFETY.CN](http://WWW.PPESAFETY.CN)

**Test & Certification Notified Body**

ECS GmbH (Notified number 1883)  
Huettfeldstrasse 50  
73430 Aalen  
Germany