

医用隔离眼罩

五大防护核心
为抗击疫情保驾护航



不带透气孔款/With perforations, 型号/Model: 2B01



带透气孔款/With perforations, 型号/Model: 2A01

三、内部装箱(尺寸、重量、每天产能)



医用隔离眼罩（护目镜）：每箱 200 个；

装箱信息：体积 0.14 立方，重量 19 千克，纸箱尺寸：66cm*37cm*37cm；

每天产量：每天生产 1 万-1.5 万个；



外包装箱子图片

医用隔离眼罩/护目镜全套资料文件

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 -----



带透气孔款/With perforations, 型号/Model: 2C01

EU type-examination certificate

C904.2HKH

CE 认证编号

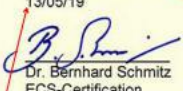
Applicant / manufacturer	Kanghua Safety Equipment Manufacturing Co., Ltd. Dianhouzhou Village Zhuge Town LANXI CITY ZHEJIANG PROVINCE P.R.CHINA
Identification of the manufacturer	HKH
Product type	Goggles, eye-protectors for occupational use, equipped with clear safety oculars
Model name	2A01, 2B01, 2C01
Standard(s) / technical rules	Essential requirements according to Annex II of the PPE Regulation (EU) 2016/425 EN 166 : 2001
Test report(s)	1001-ECS-09, 2131-ECS-19 / MR 21311-ECS-19
Materials and specifications	Safety plates: polycarbonate Frames: PVC Luminous transmittance NA 89%
Marking	HKH 1 B - 166 B CE

满足欧盟标准

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 2024-03.

ECS GmbH
Notified Body 1883
13/05/19


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

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海门镇工业功能区B区		
生产场所	浙江省金华市兰溪市海门镇工业功能区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：医用隔离眼罩予以备案，备案号：浙金械备20200014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）

金华市市场监督管理局




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20200014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：	91330781MA29U7X2R
备案人注册地址：	浙江省金华市兰溪市诸葛工业园区B区
生产地址：	金华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：	医用隔离眼罩
型号/规格：	2A01 2B01 2C01 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、血液飞溅或泼溅。
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-医用隔离眼罩（护目镜）的检测报告——欧盟检测报告

ECS 

ECS GmbH - European Certification Service
Augenschutz und Persönliche Schutzausrüstung
Laserschutz und Optische Messtechnik

Test Report

No. 2131-ECS-19

Responsible / Contact person: Sonja Forstreuter
Phone: +49 (0)7361 9754344
Fax: +49 (0)7361 5562434
E-mail: sonja.forstreuter@ecs-eyesafe.de
Web: www.ecs-eyesafe.de

Test lab accredited by DAkkS D-PL-15590-02-06
Notified by the Central ZLS-NB-0304
Authority of the Federal States
for Safety Technologies (ZLS)

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

Manufacturer

Test report contains	Main part and 1 measurement report
Number of pages in this test report	6
Product	Safety goggles for occupational use
Arrival of samples	Apr 17, 2019
Period of testing	Apr 25 to May 03, 2019
Test specifications (Standards)	EN 166 : 2001
Remarks	Retests for recertification

The results described in this test report refer to the mentioned test samples, exclusively. A copy of the test report, complete or in extracts, is not allowed without any written permission of the ECS GmbH Aalen.

Aalen, 10 May 2019

Dipl.-Ing. (FH) Sonja Forstreuter
Head of ECS-test lab

Adresse: Hütteldstraße 50
73430 Aalen

Geschäftsführer:
Dr. Bernhard Schmitz

Registereintrag:
Urn HRB 720831

USt-IdNr:
DE253376674

Test objects, tests and results

Based on the tables as written in the standards EN 166, the main part assigns the test samples to the named tests. The test results are documented according to the named standards.

Signs and symbols

The requirements are described in EN 166

- + meet the requirements
- do not meet the requirements
- / not tested
- n.a. not applicable
- n.v. not available
- G borderline case
- Ab interruption of the testing sequence
- BO Base out
- BI Base in
- RT Room temperature

Whenever the dioptric power of the surface is stated, this value was calculated using the formula $F=0,523/r$, where "r" is the radius of the curved surface.

The relative measurement uncertainties of the applied optical metrological instruments correspond to the required one in EN 167.

Unless stated otherwise, the measurements were carried out in the main viewing point of the specimens and, in the case of lenses with corrective power, at the applicable reference point.

Test results

The annexes document the test results of each individual measurement. All results printed in bold and italic type document that the test sample did actually not meet the requirements which are demanded in the specified standards.

Samples and summary of the test results

Type:	Safety goggles 2A01, 2B01 and 2C01					
Test report:	21311-ECS-19				Samples 19131-7 to -9 will be archived	
Number of delivered samples:	9					
Number of test samples:	6					
Test sequence	Requirement	Tests according to				Samples 19131-1 to -6
		EN	Clause	EN	Clause	
1	Marking	166	9.2			+
2	Information delivered by the manufacturer / applicant	166	10			n.a.
3	Identity check	J.	J.			+
4	Quality of surface and material	166	7.1.3	167	5	+
5	Field of vision	166	7.1.1	168	18	+
6	Side protection	166	7.2.8	168	19	+
7	Spherical + astigmatic refractive powers	166	7.1.2	167	3.2	+
8	Prism imbalance	166	7.1.2	167	3.2	+
9	Luminous transmittance rel. NA / D65	166	7.1.2	167	6	+
10	Diffusion of light	166	7.1.2	167	4	+
11	Protection against high speed particles, medium energy impact (B)	166	7.3.4	168	9	+
See the measurement report 1 for the individual results of each test sample.						

Samples and summary of the test results

Type:	Safety goggles 2A01, 2B01 and 2C01					
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8	Prism imbalance	166	7.1.2	167	3.2	+
9	Luminous transmittance rel. NA / D65	166	7.1.2	167	6	+
10	Diffusion of light	166	7.1.2	167	4	+
11	Protection against high speed particles, medium energy impact (B)	166	7.3.4	168	9	+
See the measurement report 1 for the individual results of each test sample.						

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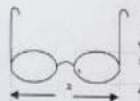
Test mark: 21311-ECS-19

Type: Safety goggles 2A01, 2B01 and 2C01

Measurement Report 1

This measurement report refers to 1001-ECS-09. Due to renewal of certificate C904.1HKH refests have been performed for recertification.




Description of the type

<p>Design:</p> 	<p>Safety goggles for occupational use, polycarbonate lens covering both eyes, three different frames made of PVC</p> <p>middle thickness of lens: 1.5 mm ± 0.05 mm</p> <p>Vertex power / dpt: Front surface: 0.0</p> <p>Model 2A01: Models 2B01 & 2C01</p> <p>a / mm: 165 a / mm: 190</p> <p>b / mm: 78 b / mm: 80</p>
<p>Frame:</p>	<p>Identification mark: CE 166 B HKH 1 B</p>
<p>Material:</p>	<p>PVC, black elastic headband</p>
<p>Lens:</p>	<p>Identification mark: none</p>
<p>Material:</p>	<p>Polycarbonate</p>
<p>Information from the producer:</p>	<p>see technical files acc to PPE-Regulation (EU) 2016/425</p>

Test mark: 21311-ECS-19

Type: Safety goggles 2A01, 2B01 and 2C01

Samples assigned to numbers

Sample number	Description	Picture
19131-1, -4 and -7	Figure 1: Model 2A01 light green transparent frame, indirect ventilation, 4 black inserts	
19131-2, -5 and -8	Figure 2: Model 2B01 clear transparent frame, direct ventilation	
19131-3, -6 and -9	Figure 3: Model 2C01 clear transparent frame, indirect ventilation, 4 white inserts	

Identity check

test	19131-1	19131-2	19131-3
reference samples / test mark	9001-13, -30 and -46 / 1001-ECS-09		
results	<p>The samples are identical to the reference samples in form, size, colour, material and transmittance</p> <p>Remark: size of the plastic rivets changed, head band is a bit broader (now 12mm), nose parts slightly smaller.</p>		

Test mark: 21311-ECS-19

Type: Safety goggles 2A01, 2B01 and 2C01

Quality of material and surface, refractive powers, prism imbalance, diffusion of light, transmission

test sample			19131		
			-1	-2	-3
quality of material and surface			+	+	+
field of vision			+	+	+
side protection			+	+	+
spherical power	R L	dpt	-0.01 -0.01	-0.01 -0.01	-0.01 -0.01
astigmatic power	R L	dpt	0.01 0.01	0.01 0.01	0.01 0.01
prism imbalance (horizontal/vertical)		cm / m	0.00 / 0.00	0.00 / 0.00	0.00 / 0.00
optical class			1	1	1
reduced luminance coefficient, diffusion of light	R L	cd/m ² lx	0.09 0.06	0.07 0.07	0.04 0.05
luminous transmittance rel NA τ		%	88.8	89.1	89.2
luminous transmittance rel D65 τ		%	88.8	89.0	89.1

Protection against high-speed particles / resistance to energy impact

sample	test temperature / °C	test point	speed / m/s	Results
19131-4	RT	left frontal / right side	120	+ +
19131-5	RT	right frontal / left side	120	+ +
19131-6	RT	left frontal / right side	120	+ +

- End of Measurement Report 1 -

Samples and summary of the test results

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10	Diffusion of light	166	7.1.2	167	4	+
11	Protection against high speed particles, medium energy impact (B)	166	7.3.4	168	9	+
See the measurement report 1 for the individual results of each test sample.						

五、生产车间真实图片



六、医用隔离眼罩（护目镜）英文使用说明书



KANGHUA SAFETY EQUIPMENT MANUFACTURING CO.,LTD

Dianhouzhou Village, Zhuge Town, Lanxi City, Zhejiang, China

USER INSTRUCTIONS

2A01/2B01/2C01

Description

The safety goggles are designed to protect the eyes against mechanical risks caused by flying particles in industry, laboratories, educational establishments, DIY activities etc.
It must be worn for the whole duration of exposure to hazards, leave the work area if dizziness or irritation occurs, or if the spectacle/goggle becomes damaged. The lenses are made of impact-resistant polycarbonate. This eye protector is not intended for welding use. The goggle (frames and lenses) is certified to meet EN166:2001 and PPE Regulation EU 2016/425.

USAGE, STORAGE, AND MAINTENANCE

In use, ensure the eye protector fits comfortably over the eyes. This eye protector should be stored in a case, out of direct sunlight, away from chemicals and abrasive substances, in a clean, dry, dust-free environment when not in use or during transportation.

To clean, rinse in 1% solution of mild detergent and dry with a dry fluff-free soft cloth. DO NOT USE abrasive cleansers. If necessary a non-aggressive household disinfectant may be used. Under normal circumstances the eye protector should offer adequate protection for 3 years from manufacturers date. The manufacturer month and year can be found on the PPE component.

WARNING

- When in contact with the skin the frame may cause allergic reactions to susceptible individuals. If this is the case doctor's advice should be sought.
- Always wear well-fitting goggle, this will encourage wearing and therefore will increase your safety.
- For optimum protection when working, wear the goggle continuously.
- Clear lenses offer no protection against optical radiation given off during welding and cutting work.
- Coloured lens only provide protection against intended protection stated on its marking (see field of application)
- Coloured lenses are not suitable for working or driving during twilight and at night.
- Coloured lenses are not suitable for looking directly into the sun.
- Do not continue using the goggle if the frame is broken or snapped.
- Do not continue using the eyewear if the lenses are dull, damaged or scratched-replace them.
- Do not continue using the eyewear if cleaning does not improve vision.
- Always replace the complete eye protectors immediately if the ocular become scratch and damage.
- The goggles for protection against high speed particles worn over standard ophthalmic spectacles may transmit impacts, thus creating a hazard to the wearer.
- Optical class 3 oculars are not intended for long term use.
- If protection against high speed particles at extremes of temperature is required then the selected goggle should be marked with the letter T immediately after the impact letter.
- If the impact letter is not followed by the letter T then the eye protector shall only be used against High speed particles at room temperature. If in doubt, consult your supplier.
- Ensure that you follow all instructions and warnings
- Improper use of this product may endanger the wearer's health.



KANGHUA SAFETY EQUIPMENT MANUFACTURING CO.,LTD

Dianhouzhou Village, Zhuge Town, Lanxi City, Zhejiang, China

- Do not modify the goggles.
- Retain this information.

Marking

The ocular and frame are marked in accordance with the requirements of EN166:2001:

HKH 1 B – 166 B CE

HKH: Identification of manufacturer

1: Highest optical class

B: Medium energy impact

EN 166 CE: EN standard

Specifications

Optical class: 1

Material lenses: polycarbonate

Frame: PVC

Headband: Fabric

Compatibility of Marking

The carrier / brow guard B, the visor B - it is the symbol which is assigned to the complete assembled Eye protectors. If symbols F, B & A are not common to both the ocular and the frame, then it is the lower Level which shall be assigned to the complete eye-protector

If protection against high speed particles at extremes of temperature is required then the selected eye-protector should be marked with the letter T immediately after the impact letter, i.e. FT, BT or AT. If the impact letter is not followed by the letter T then the eye protector shall only be used against high speed particles at room temperature.

Cleaning and Storage

Flush frame with lukewarm water, then wipe it with dry cloth. Use compressed air to blow dust on ocular surface. If the ocular is scratched, it must be replaced. DO NOT use solvents. Store this product in a dry place, sheltered from sun light.

Packing/Transportation

Pack the safety goggles in cartons when transporting.

Service life

The period of obsolescence of this product is 3 year.

Manufacturer information

**KANGHUA SAFETY EQUIPMENT MANUFACTURING
CO.,LTD**

Dianhouzhou Village, Zhuge Town, Lanxi City,
Zhejiang, China

Technical File Ref: 2A01/2B01/2C01

Date: April.18.2019



**KANGHUA SAFETY EQUIPMENT
MANUFACTURING CO.,LTD**

Dianhouzhou Village, Zhuge Town, Lanxi City, Zhejiang, China

Declaration of conformity

Hereby, KANGHUA declares that safety goggles 2A01/2B01/2C01 is in compliance with Regulation (EU) 2016/425 The full text of the EU declaration of conformity is available at the following internet address: www.xxxxxx

Test & Certification Notified Body

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

七、销售单位资料

制造商出具授权函

我方 兰溪市康华防护用品有限公司，主要营业地点设在 浙江省金华市兰溪市诸葛工业功能区B区，我们获悉按中华人民共和国法律成立的 江西腾格科技有限公司，将以我方的产品对贵单位销售我方产品，我们特做如下声明：

(1) 同意 江西腾格科技有限公司 在中华人民共和国境内以 兰溪市康华防护用品有限公司 的 防护眼罩、防护面罩、防护眼镜 的产品进行销售。

我方于 2020年2月1日 签署本文件 江西腾格科技有限公司 于 2020年2月1日 接受此文件，有效期：从 2020年2月1日 至 2020年6月30日

制造商名称：兰溪市康华防护用品有限公司

授权日期：2020年2月1日



康华公司为生产单位，只有生产和产品资质，没有医疗器械的销售资质，腾格具备医疗器械的销售资质，所以签订合同、打款均有江西腾格公司执行；

证照编号: 011120035200



营业执照

(副本)₁₋₁

统一社会信用代码 91360111MA35GUNW4B

名称 江西腾格科技有限公司
类型 有限责任公司(自然人独资)
住所 江西省南昌市青山湖区北京东路1463号精英汇商业金融2#-605室(第6层)
法定代表人 陈敬业
注册资本 贰佰万元整
成立日期 2016年03月17日
营业期限 2016年03月17日至长期
经营范围 计算机软硬件开发; 医疗器械、计算机软硬件销售; 室内外装饰装修工程; 机电设备销售、安装、维修。(依法须经批准的项目, 经相关部门批准后方可开展经营活动)



提示: 请于每年1月1日至6月30日通过“国家企业信用信息公示系统(江西)”报送年报, 即时信息按规定公示。

登记机关



企业信用信息公示系统网址:

中华人民共和国国家工商行政管理总局监制

第二类医疗器械经营备案凭证

备案编号：赣洪食药监械经营备 20165078 号

企业名称	江西腾格科技有限公司
法定代表人	陈敬业
企业负责人	陈敬业
经营方式	批零兼营
住所	江西省南昌市青山湖区北京东路 1463 号精英汇商业金融 2#-605（第 6 层）
经营场所	江西省南昌市青山湖区北京东路 1463 号精英汇商业金融 2#-605（第 6 层）
库房地址	江西省南昌市青山湖区北京东路 1463 号精英汇商业金融 2#-605（第 6 层）
经营范围	II--6801 基础外科手术器械、6803 神经外科手术器械、6807 胸腔心血管外科手术器械、6809 泌尿肛肠外科手术器械、6810 矫形外科（骨科）手术器械、6815 注射穿刺器械、6820 普通诊察器械、6821 医用电子仪器设备、6822 医用光学器具、仪器及内窥镜设备、6823 医用超声仪器及有关设备、6824 医用激光仪器设备、6825 医用高频仪器设备、6826 物理治疗及康复设备、6827 中医器械、6830 医用 X 射线设备、6831 医用 X 射线附属设备及部件、6833 医用核素设备、6834 医用射线防护用品、装置、6841 医用化验和基础设备器具、6845 体外循环及血液处理设备、6846 植入材料和人工器官、6854 手术室、急救室、诊疗室设备及器具、6855 口腔科设备及器具、6856 病房护理设备及器具、6857 消毒和灭菌设备及器具、6863 口腔科材料、6864 医用卫生材料及敷料、6865 医用缝合材料及粘合剂、6866 医用高分子材料及制品、6870 软件

备案部门（公章）

备案日期：2016 年 12 月 16 日





开票账户信息（13%的增值税专用发票）：

名称：江西腾格科技有限公司

税号：91360111MA35GUNW4B

账号：3605 0153 0162 0000 0262

开户行：中国建设银行南钢支行

地址：江西省南昌市高新开发区紫阳大道泰豪科技广场 A 座 2119 室

不开票账户：

姓名：陈敬业

账号：6217 0020 2007 6915 982

开户行：中国建设银行南钢支行



需要下单的人，联系人： 刘先生 13173987816