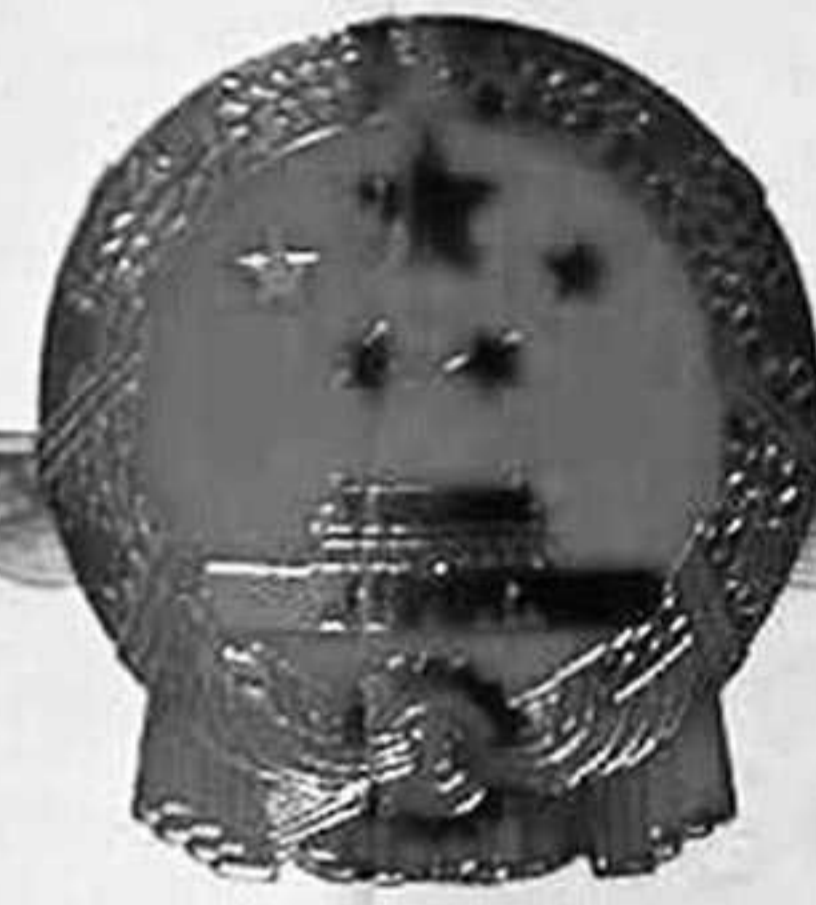


- 医用……
- 1、工厂营业执照
 - 2、企业生产许可证
 - 3、产品检验报告
 - 4、医疗器械注册书
 - 5、产品说明书、标签
 - 6、产品批次/号
 - 7、产品样品图片及外包装图片
 - 8、产品质量安全书

证照编号: A031017379



统一社会信用代码
91360125568659430L

营业执照



扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。

名称 南昌益盾科技有限公司
类型 有限责任公司(自然人投资或控股)
法定代表人 樊荣生
经营范围 口罩销售, 第一类医疗器械医用隔离面罩和医用隔离眼罩的生产(凭许可证经营)和销售; 眼镜研发; 眼镜、护目镜、服装、日用百货、电子产品、母婴用品、玩具、医疗器械(III类医疗器械限在医疗器械经营企业许可证范围内经营)的销售; 化妆品的批发、零售(以上项目国家有专项规定的凭许可证、资质证或其他批准文件经营)(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)

注册资本 贰仟万元整
成立日期 2011年01月17日
营业期限 2011年01月17日至2031年01月16日
住所 江西省南昌市西湖区朝阳洲中路利民佳苑公建2号楼A307室

登记机关

2020年03月18日



第一类医疗器械生产备案凭证

备案编号：赣洪械生产备 20200011 号

企业名称	南昌益盾科技有限公司		
住 所	江西省南昌市西湖区朝阳洲中路利民佳苑公建 2 号楼		
生产地址	江西省南昌市西湖区朝阳洲中路利民佳苑公建 2 号楼		
法定代表人	樊荣生	企业负责人	樊喆
生产范围	I 类：14 注输、护理和防护器械***		
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	赣洪械备 20200075 号	2020-02-17



备案部门（公章）
备案日期：2020年02月17日



中国认可
国际互认
检测
TESTING
CNAS L7901

检验检测报告

TEST REPORT

STFWT20200803

产品名称 Product Name	医用隔离眼罩
委托单位 Trust Unit	南昌益盾科技有限公司
生产单位 Manufacturer	南昌益盾科技有限公司
检验检测类别 Test Category	委托送样检验



SPC 江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS



扫描全能王 创建

检 验 检 测 报 告

Test Report



防伪查询

共 2 页 第 1 页

Page 1 of 2

STFWT20200803

产品名称 Product Name	医用隔离眼罩	规格型号 Specification Type	—
		商 标 Trademark	益盾
委托单位 Trust Unit	南昌益盾科技有限公司	电 话 Tel	18911866617
生产单位 Manufacturer	南昌益盾科技有限公司	样品等级 Sample Grade	—
样品数量 Sample Quantity	2 个	送样日期 Sample Receiving Date	2020-02-14
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	—
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	GB 14866-2006 《个人用眼护具技术要求》		
检验检测结论 Test Conclusion	<p style="text-align: center;">样品经检验，所检项目符合 GB 14866-2006 标准规定的要求。</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p style="text-align: right;">签发日期: 2020-02-18 Signature Date: (1)</p>		
备 注 Remarks	本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。 本报告仅对来样负责。		

批准:
Approver

陈敏

审核:
Examiner

杨森

主 检:
Major tester

凌青梅

检验检测结果 Testing Results

STFWT20200803

共 2 页 第 2 页
Page 2 of 2

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	有机镜片表面 耐磨性能/%	—	按 6.5 规定的方法测试后, 镜片 表面磨损率 H 应低于 8%。	1.88	合格
2	化学雾滴 防护性能	—	按 6.8 规定的方法测试后, 若镜片 中心范围内试纸无色斑出现, 则认 为合格。	经测试, 镜片中心范围内试 纸无色斑出现。	合格

样品图片

测试样品




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检测专用

第一类医疗器械备案信息表

备案号：赣洪械备20200075号

备案人名称:	南昌益盾科技有限公司
备案人组织机构代码:	91360125568659430L
备案人注册地址:	江西省南昌市西湖区朝阳洲中路利民佳苑公建2号楼
生产地址:	江西省南昌市西湖区朝阳洲中路利民佳苑公建2号楼
代理人:	南昌益盾科技有限公司
代理人注册地址:	江西省南昌市西湖区朝阳洲中路利民佳苑公建2号楼
产品名称:	医用隔离眼罩
型号/规格:	蓝白、百叶窗、软边小风镜、四珠全封闭、大框全封闭
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:	 <p>南昌市行政审批局 备案日期: 2020年02月16日 行政审批专用章 (5)</p>
变更情况:	

第一类医疗器械备案凭证

南昌益盾科技有限公司：

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：赣洪械备20200075号。



南昌市行政审批局

(盖章)

行政审批专用章

日期：2020年02月16日

133x190mm 正

医疗器械说明书

生产企业/备案人名称	南昌益盾科技有限公司		联系方式	4006668810 18397912796
备案人住所	江西省南昌市西湖区朝阳洲中路利民佳苑公建2号楼		邮政编码	330000
生产及售后服务单位地址	江西省南昌市西湖区朝阳洲中路利民佳苑公建2号楼			
产品通用名称	医用隔离眼罩	型号规格	蓝白、百叶窗、软边小风镜、四珠全封闭、大框全封闭	
医疗器械备案凭证编号	赣洪械备20200075号	售后服务单位	南昌益盾科技有限公司	
产品技术要求编号	赣洪械备20200075号	生产备案凭证编号	赣洪械生产备20200011号	

【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。

【适用范围】

用于医疗机构门诊、病房、检验室等作普通隔离。

【使用方法】

打开包装，取出隔离眼罩，检查其完好性，佩戴于头部，防护眼部。

【说明书的编制及修改日期】

说明书编制于 2020 年 2 月 16 日

【禁忌症、注意事项、警示及提示性说明】

1. 单包装破损，严禁使用；
2. 本产品为一次性使用，用后销毁；
3. 产品规格、数量、生产日期或生产批号详见包装或标签。
4. 产品未经灭菌处理，有效期三年。

【医疗器械标签所用的图形、符号、缩写等内容的解释】



注意，参阅附件



不得二次使用



参考使用说明



非灭菌

【产品维护和保养方法，特殊储存条件、方法】

应贮存在空气相对湿度不超过 80% 且无腐蚀性物质侵蚀、通风良好的室内。

生产批号：20200218

生产日期：20200218

133x190mm 反

User guide of the medical equipment

Manufacture/recorder name	Nanchang Yidun Technology Co., Ltd	Tel.	4006668810 18397912796
Address	Limin Jiayuan No.2 Public Building, Chaoyangzhou Middle Road, Xihu District, Nanchang City, Jiangxi Province		Postal code 330000
Production and after-sales service unit address	Limin Jiayuan No.2 Public Building, Chaoyangzhou Middle Road, Xihu District, Nanchang City, Jiangxi Province		
The general name of the product	Safety Goggles	Model specification	Blue-white, window-shades, small goggles with soft edges, full close of four pearls, and full close in the big frame
Recording certificate number of medical equipment	Ganhong equipment recording No. 20200075	After-sales service unit	Nanchang Yidun Technology Co., Ltd
Product technical requirement number	Ganhong equipment recording No. 20200075	Production recording certificate number	Ganhong equipment production recording No.20200011

【Product description】

It is composed of shields made from high polymer materials, foam bars, and fixed devices. It is nonsterile and disposable for developing a protective role for checking and treatment in medical institutions. It obstructs body fluid, blood splashing or spilling.

【Range of application】

It is used for the outpatient services, wards, and checkout rooms in medical institutions for common isolation.

【How to use】

Open the package, take out the isolate eye patches, check completeness, and wear it on the head to protect eyes.

【Compilation and modification date of the user guide】

The user guide was compiled on February 16, 2020.

【Contraindications, attentions, warnings, and indicative instructions】

1. If the package is broken, don't use it;
2. The product is disposable, please destroy it after using;
3. The product specification, quantity, date of production or batch number of production see the package or label.
4. The product is not disposed by sterilization with the validity of three years.

[Explanations of graphs, symbols and abbreviations fused by the medical instrument labels]



Notice, attached documents



No secondary use



Reference instruction



Non sterile

【Product maintenance and conservation method, special storage conditions and methods】

It should be stored in the room with relative air humidity no less than 80%, no corrosive materials and good ventilation.

Production batch number: 20200326 Date of production: 20200326

合格证

南昌益盾科技有限公司
本产品经检验合格准予出厂

产品名称：医用隔离眼罩
产品规格：四珠全封闭
产品型号：YD 2006
产品尺寸：14.99cm X 7.18cm
产品材质：镜框：聚氯乙烯（PVC）
镜片：聚碳酸酯（PC）
产品描述：非无菌提供，一次性使用
执行标准：GB14866-2006
出厂日期：2020年4月20日
保质期：3年
生产等级：合格品
生产批号：20200430
检验员：01-023
产地：江西·南昌
生产企业：南昌益盾科技有限公司
公司地址：江西省南昌市西湖朝阳
洲中路利民佳苑公建2号楼
服务热线：400-666-8810



Qualified Certificate

Nanchang Yidun Technology Co., Ltd.

The product is allowed to leave the
factory after passing the inspection

Product name: Safety Goggles
Product specifications: Four beads
Product model: YD 2006
Product specifications: 14.99cm x 7.18cm
Product material: Picture frame (PVC)
Lens (PC)
Product description: Non sterile, disposable
Date of production: April 20, 2020
Shelf Life: 3 years
Production grade: Qualified products
Batch number: 20200420
Inspector: 01-023
Place of Origin: Nanchang JiangXi
Production company: Nanchang Yidun
Technology Co., Ltd
Address: Building No.2 Gongjian, Liming
Jiayuan, Road Chaoyangzhou
Nanchang City, Jiangxi Province
China







Product Description
Name: Safety Goggles
Country Of Origin: China
Reference Standard:
GB14886-2006
CE EN166, FDA
Company:
Nanchang Yidun Technology Co., Ltd.
Address: Building No.2 Gonglian,
Liming Jixuan,
Road chaoyangzhou, Nanchang City
Jiangxi Province, China
Manufacturing Date: 03/26/2020
Shelf Life: 3 years
Test Results: Qualified
Tel: 0086-18397912796

Product Description
Name: Safety Goggles
Country Of Origin: China
Reference Standard:
GB14886-2006
CE EN166, FDA
Company:
Nanchang Yidun Technology Co., Ltd.
Address: Building No.2 Gonglian,
Liming Jixuan,
Road chaoyangzhou, Nanchang City
Jiangxi Province, China
Manufacturing Date: 03/26/2020
Shelf Life: 3 years
Test Results: Qualified
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Product Description
Name: Safety Goggles
Country Of Origin: China
Reference Standard:
GB14886-2006
CE EN166, FDA
Company:
Nanchang Yidun Technology Co., Ltd.
Address: Building No.2 Gonglian,
Liming Jixuan,
Road chaoyangzhou, Nanchang City
Jiangxi Province, China
Manufacturing Date: 03/26/2020
Shelf Life: 3 years
Test Results: Qualified
Tel: 0086-18397912796





尺寸: 82 x 34.5 x 50 CM

净重: 16 kg

毛重: 21 kg

规格: 200 副

外箱尺寸

产品质量安全书

我公司生产的产品从设计、生产、检测到产品包装，运输售后服务各环节，产品质量严格按照国标、行标、企标要求进行出厂检验，不合格产品决不出厂。不定期邀请有关专家来公司监督、指导工作，来把质量关。

1. 材料采购

采购部严格按照质量手册及采购控制程序的要求进行供应商评价及原材料采购，每批原材料检验合格后方可入库和投入生产。

2. 生产

生产部严格按照公司质量管理体系及产品工艺技术文件的要求组织生产，确保生产产品的质量。

3. 检验

质量管理部严格按照产品原材料检验规程、过程检验规程、成品检验规程的要求进行原材料、过程产品、成品的检验，确保只有合格的原材料、过程产品、成品才能放行和出厂。

4. 不合格品的控制

质量管理部根据不合格品控制程序的要求对原材料、过程产品、成品、及已交付的产品中发现的不合格品进行标识、隔离、评审和处置，必要时采取纠正措施，确保相应的不合格不发生或降低发生的概率。

5. 包装与运输

公司产品在设计和开发的过程中进行包装设计，至少采用两层包装，确保产品在运输过程中的产品质量，并于选择有资质承运单位，签订承运合同，确保运输过程中产品质量得到有效控制，明确双方应承担的责任和义务。

6. 本公司保证提供的产品全新且符合国标相关标准，并满足采购协议规定的产品。





Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

NANCHANG.YIDUN TECHNOLOGY CO.LTD

**Building No.2 Liming Jiayuan,Chaoyangzhou Road Middle, Nanchang
City, JIANGXI, 330000, CHINA**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

HEALREG SERVICE INC

Owner/Operator Number: 10066254

Device Listing#: See annex

HEALREG SERVICE INC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. HEALREG SERVICE INC makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. HEALREG SERVICE INC assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, HEALREG SERVICE INC is not affiliated with the U.S. Food and Drug Administration.



A handwritten signature in black ink, appearing to read 'John Foss'.

Chief engineer

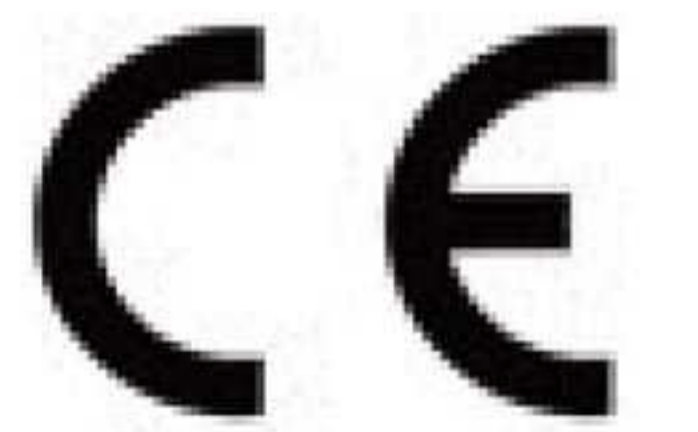
Issued: April 1, 2020

Expiration Date: December 31, 2020



Certificate

No. ICR Polska/M6007033



Name and address of certificate owner:

Nanchang Yidun Technology Development Coporation Ltd
Building No.2 Liming Jiayuan,Chaoyangzhou Road Middle,
Nanchang City,Jiangxi Province

Name and address of manufacturer:

Nanchang Yidun Technology Development Coporation Ltd
Building No.2 Liming Jiayuan,Chaoyangzhou Road Middle, Nanchang City,
Jiangxi Province

Product name:

Safety Goggles

Product types:

YD2001,YD2002,YD200X (X=3 to 10)

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation MDD 93/42/EEC

EN 166:2002

The certification process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

No. of test reports:

MICEZ-2005-0324S-MDD

Certificate issue date:

20.03.2020

Expiration date:

19.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-0124.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.



Director: Rafał Kalinowski

Warsaw, 20. 03. 2020



ICR Polska Co. Ltd.

ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com



3203692-Test Report.

Introduction.

This report has been prepared by S Macdonnell and relates to the activity detailed below:

Job/Registration Details	Client Details
Job number: 3203692 Job type: Testing Samples Submitted Start Date: 29 April 2020 Test type: Direct Sample ID: 10189584 Registration: CE 728519 Scheme: PPE Regulation and EU recommendation 2020/403 Protocol: P2323 Scheme Mgr: Nathan Shipley	Nanchang Yidun Technology Co.,Ltd Limin Jiayuan No.2 Public Building, Chaoyangzhou Middle Road, Xihu District, Nanchang Jiangxi China

The report has been approved for issue by M Mayo – Testing Team Manager

Approved For Issue	
	Issue Date: 1 May 2020

Objectives.

This is limited testing to only certain clauses or sub-clauses of the standard but these have been followed in full, as defined. This technical specification is applied to safety eyewear for use by healthcare workers, first responders and other personnel involved in the efforts to contain the COVID-19 virus and avoid its further spread and in relation to the EU Commission recommendation sheet 2020/403.