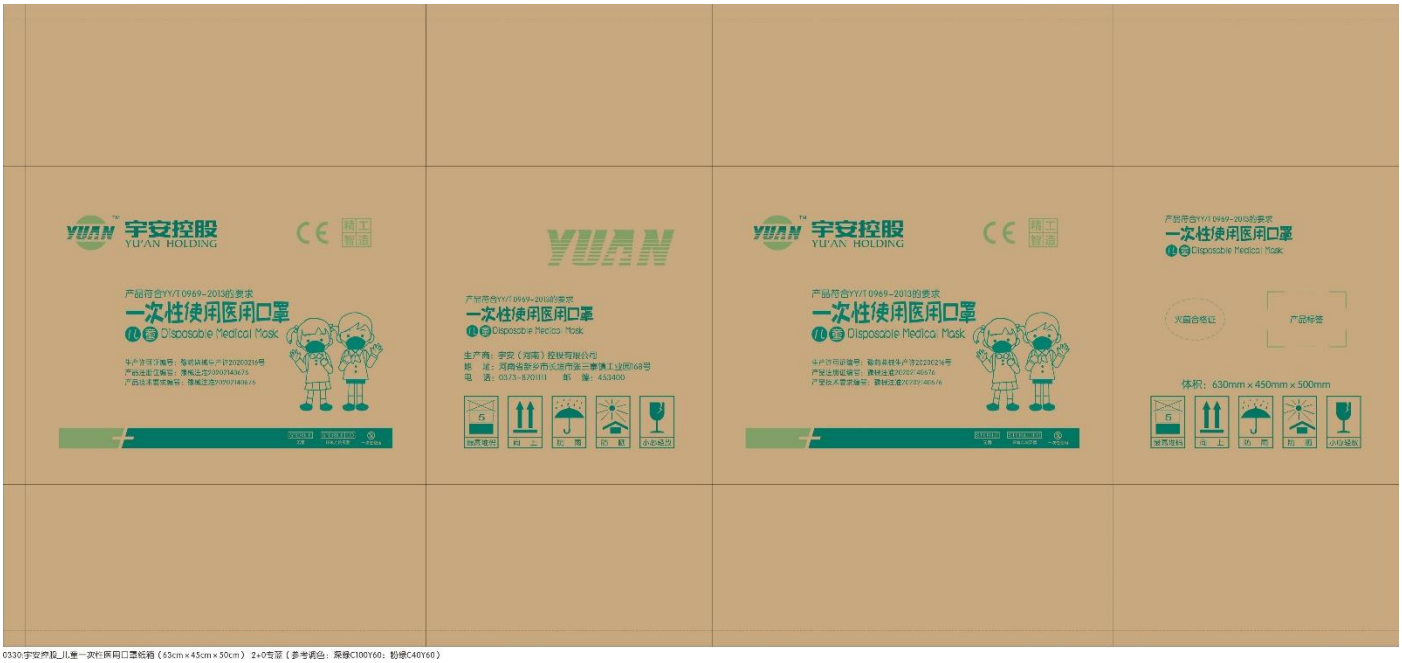
- 一次性使用医用口罩 小包装 中文版

- 一次性使用医用口罩 小包装 英文版

- 一次性使用医用口罩 外箱包装 中文版

0330-宇安病医_一次性口罩纸箱（63cm×45cm×50cm） 2+0专版（参考调色：黑版C96M60Y15；浅版C50M18）



0330-宇安控股_儿童一次性医用口罩纸箱（63cm×45cm×50cm） 2+0专版（参考调色：深绿C100Y60；粉绿C40Y60）

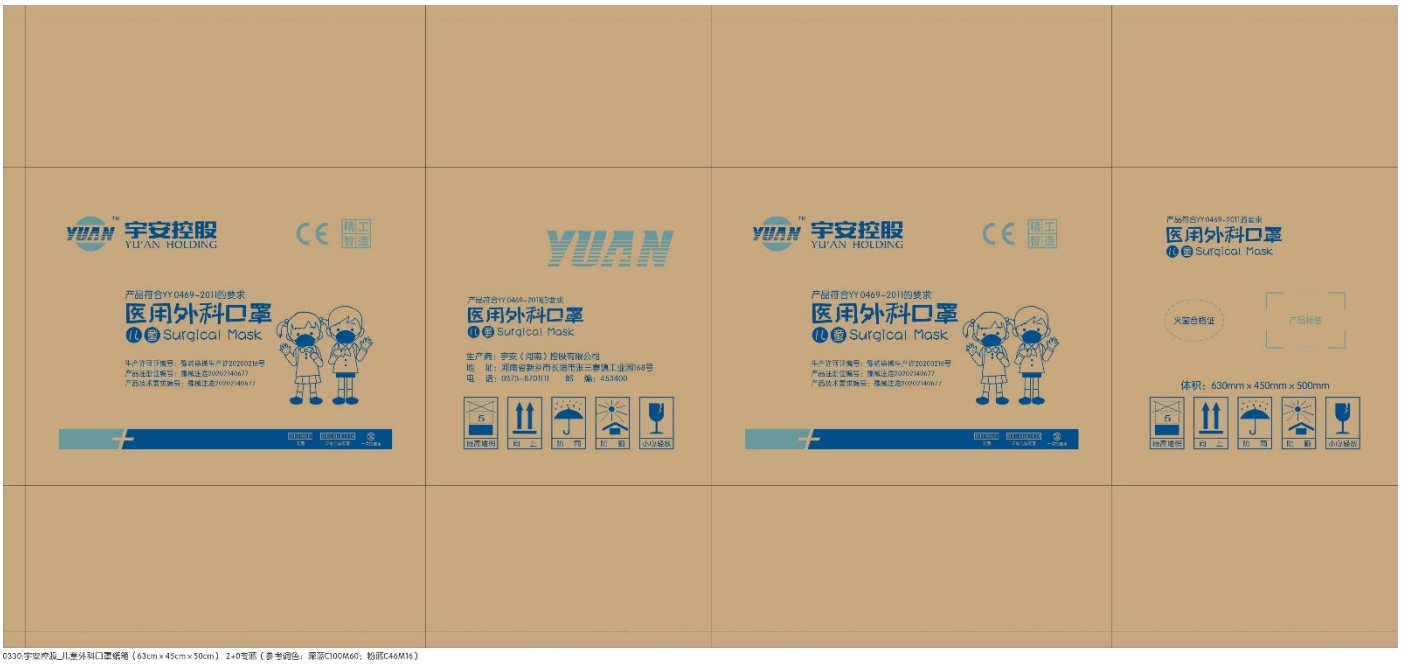
- 一次性使用医用口罩 外箱包装 英文版

- 医用外科口罩 小包装 中文版

3.18 **医用外科口罩_挂耳型纸塑袋** 成品尺寸：280×160(240×130)mm；左右侧封口各20mm；上下各15mm；
2+0 专蓝（印刷色值：C80M5Y20）+专银（合资或进口油墨）

- 医用外科口罩 外箱包装 中文版

0222-宇安控股_外科口罩纸箱（63cm × 45cm × 500cm） 2+0专版（参考调色：黑版C96M60Y15；浅版C50M18）



0330-宇安控股_儿童外科口罩纸箱（63cm × 45cm × 50cm） 2+0专版（参考调色：黑版C100M60；粉版C46M16）

International Certification Registrar International Certification Registrar International Certification Registrar

Certificate

ICR Polska/CE/V/ M3100135

Name and address of certificate owner:	Yu An (Henan) Holding Limited Company No. 168, Industrial Park, ZhangSanZhai Town, ChangYuan City, XinXiang City, HeNan province.
Name and address of Registered Manufacturer:	Yu An (Henan) Holding Limited Company No. 168, Industrial Park, ZhangSanZhai Town, ChangYuan City, XinXiang City, HeNan province.
Product name:	Disposable Medical Protective Clothing
Product types:	160, 165, 170, 175, 180, 185
Product trademark:	YUAN 宇安控股 YU'AN HOLDING

- This certificate confirms that the product meets the requirements of the following standard
- The conformity was demonstrated based on following standard(s) listed by European Commission as harmonized with **Directive 93/42/EEC.**

EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)	Class I according Rule 1 of Annex IX of Directive 93/42/EEC	EN 14126:2003

The certification has been carried out In accordance with Individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report(s) No.:	BG2003TR9184S06
Test conducted by:	Shenzhen Bta Produce Testing Co.,Ltd.
Certificate issue date:	03.04.2020
Expiration date:	02.04.2025

NOTE:

- This certificate refers to the above mentioned produce and its conformity in regards of above mentioned standard(s) was proven on test sample
- This certificate does not Imply meeting all essential requirements, assessment of the series-production or any other restricted Notifled Bodies conformity assessment procedure appropriate for the product
- This certificate holder shall use this certiflcate in connection to declaration of conformity and technical data relevant for the product the certiflcate was Issued

Certificate modifications:n/a

INTERNATIONAL CERTIFICATION REGISTRAR ICR REGISTERED FIRM JEDNOSTKA NOTYFIKOWANA Nr 2703

CE

ICR Polska Co.Ltd.
Plac Przymierza 6
03-944 Warsaw
www.icrpolska.com
e-mail: icrpolska@icrqa.com

Director: Rafal Kalinowski

Warsaw, 03. 04. 2020.

- CE 认证

CERTIFICATE OF CONFORMITY

According to MDD 93/42/EEC

Applicant Name	:	Yu an (Henan) Holding Limited Company
Applicant Address	:	No. 168, Industrial Park, zhangsanzhai Town, Changyuan City, Xinxiang City, Henan Province,China
Manufacturer by	:	Yu an (Henan) Holding Limited Company
Manufacturer's Address	:	No. 168, Industrial Park, zhangsanzhai Town, Changyuan City, Xinxiang City, Henan Province,China
Product Description	:	Disposable Medical Mask

This is to certify that the product identified below is in compliance with the essential requirements of the following standards:

EN ISO 15223-1:2016
EN 1041:2008
EN ISO 14971:2012
EN ISO 10993-1:2009
EN 14683:2019+AC:2019

Reviewed by:

Signed by: Louix Xiong

QC Manager

Issued by:

COPPER EMC

BEIJING COPPER TECHNOLOGY CO.,LTD.

CE

Issued Date: May 8, 2020

This is the result of tests that were carried out from the submitted product sample(s) in conformity with the specification of the respective standards. The certificate holde right to affix the CE-Mark on the inspected product only when the product is comp plying with the required standards.

Certificate No. CE2020508-2

CERTIFICATE OF CONFORMITY

According to MDD 93/42/EEC

Applicant Name	:	Yu an (Henan) Holding Limited Company
Applicant Address	:	No. 168, Industrial Park, zhangsanzhai Town, Changyuan City, Xinxiang City, Henan Province,China
Manufacturer by	:	Yu an (Henan) Holding Limited Company
Manufacturer's Address	:	No. 168, Industrial Park, zhangsanzhai Town, Changyuan City, Xinxiang City, Henan Province,China
Product Description	:	Disposable Surgical Mask

This is to certify that the product identified below is in compliance with the essential requirements of the following standards:

EN ISO 15223-1:2016
EN 1041:2008
EN ISO 14971:2012
EN ISO 10993-1:2009
EN 14683:2019+AC:2019

Reviewed by:

Signed by: Louix Xiong

QC Manager

Issued by:

COPPER EMC

BEIJING COPPER TECHNOLOGY CO., LTD.

CE

Issued Date: May 8, 2020

This is the result of tests that were carried out from the submitted product sample(s) in conformity with the specification of the respective standards. The certificate holder has the right to affix the CE-Mark on the inspected product only when the product is completely complying with the required standards

Certificate No. CE2020508-1

- 宇安控股营业执照

统一社会信用代码
91410728MA481B680B

营业执照

（副 本） 1-1

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 宇安（河南）控股有限公司

类 型 有限责任公司(自然人投资或控股)

法定代表人 江广生

经营范围 控股公司服务。第Ⅰ、Ⅱ、Ⅲ类医疗器械的生产、销售、加工。橡胶制品、医用高分子材料、化工原料、农产品、水产品、食品、医疗卫生产品及其他材料的电子辐照灭菌消毒。医疗卫生产品及其材料的环氧乙烷灭菌消毒。卫生用品、抗(抑)菌剂(液体)、清洗液、消毒液、医疗灭菌指示物及包装、医用封口机及相关设备、空气消毒设备、房屋消毒设备、医疗灭菌检测器械、消毒器械的研发生产及销售。计算机软硬件及辅助设备的开发及销售。卫生材料制造。无纺布制品、塑料制品、家用电子电器、机械设备及配件销售。技术咨询。贸易咨询。厂房建设。房屋及场地租赁。物业管理。仓储服务。医疗器械的技术开发、技术转让、技术咨询和技术服务。组织文化交流活动。礼仪庆典服务。展览展示服务。会务会展。货物或技术进出口（国家禁止或涉及行政审批的货物和技术进出口除外）。(以上经营范围：危险化学品除外)。涉及许可经营项目，应取得相关部门许可后方可经营（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 伍仟万圆整

成立日期 2020年02月06日

营业期限 长期

住 所 河南省新乡市长垣市张三寨镇工业园168号

登记机关 长垣市市场监督管理局 4107281020393

2020 年 03 月 17 日

http://www.gsxt.gov.cn 市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告

国家企业信用信息公示系统网址:

国家市场监督管理总局监制

- 宇安控股医疗器械生产许可证

医疗器械生产许可证

许可证编号：豫药监械生产许20200216号

企业名称：宇安（河南）控股有限公司

生产地址：河南省新乡市长垣市张三寨镇工业园168号

原分类目录：6864;新分类目录：14※

法定代表人：张帅

生产范围：

企业负责人：张帅

住 所：河南省新乡市长垣市张三寨镇工业园168号

发证部门：河南省药品监督管理局

有效期限：至 2021 年 03 月 08 日

发证日期：2020 年 03 月 30 日

1.2.156.3005.2.11410000MB1912677J037.11410000MB1912669P.41000020200000166.001.Z

国家食品药品监督管理总局制

- 宇安控股海关备案

海关进出口货物收发货人备案回执

企业名称	宇安（河南）控股有限公司
统一社会信用代码	91410728MA481B680B
海关备案日期	2020-04-16
海关编码	41079619AK
检验检疫备案号	4161100093
有效期	长期

中华人民共和国海关 新乡海关 进出口货物收发货人备案专用章

2020年4月16日

自然人、法人或者非法人组织可通过“中国海关企业进出口信用信息公示平台”（http://credit.customs.gov.cn）或者“互联网+海关”（http://online.customs.gov.cn）查询海关公示的企业信息。

- 医疗器械生产产品登记表

医疗器械生产产品登记表

第1页，共1页

企业名称	宇安（河南）控股有限公司
许可证编号	豫药监械生产许20200216号
许可证有效期限	2020年03月30日 至 2021年03月08日
生产范围	原分类目录：6864※
生产范围(新分类目录)	新分类目录：14※

生产产品列表

序号	产品名称	注册号	登载日期	备注
1	一次性使用医用口罩	豫械注准20202140676	2020/03/30	应急 有效期至2021-03-08
2	医用外科口罩	豫械注准20202140677	2020/03/30	应急 有效期至2021-03-08

发证部门（公章）：

2020年03月30日

1.2.156.3005.2.11410000MB1912677J037.11410000MB1912669P.4100002020000166.001.Z

- 一次性使用医用口罩 医疗器械注册证

中华人民共和国医疗器械注册证

注册证编号：豫械注准 20202140676

注册人名称	宇安（河南）控股有限公司
注册人住所	河南省新乡市长垣市张三寨镇工业园 168 号
生产地址	河南省新乡市长垣市张三寨镇工业园 168 号
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用医用口罩
型号、规格	型号：系带型、挂耳型；规格：大号、中号、小号。
结构及组成	产品由口罩体、鼻夹、口罩带组成，其中口罩体由无纺布及聚丙烯熔喷布制成，鼻夹由可塑性材料制成，口罩带由弹性带或无纺布制成。
适用范围	供临床各类人员在非有创操作过程中佩戴，覆盖住使用者的口鼻及下颌，为防止病原体微生物、颗粒物等的直接透过提供一定物理屏障。
附　件	产品技术要求
其他内容	无
备　注	

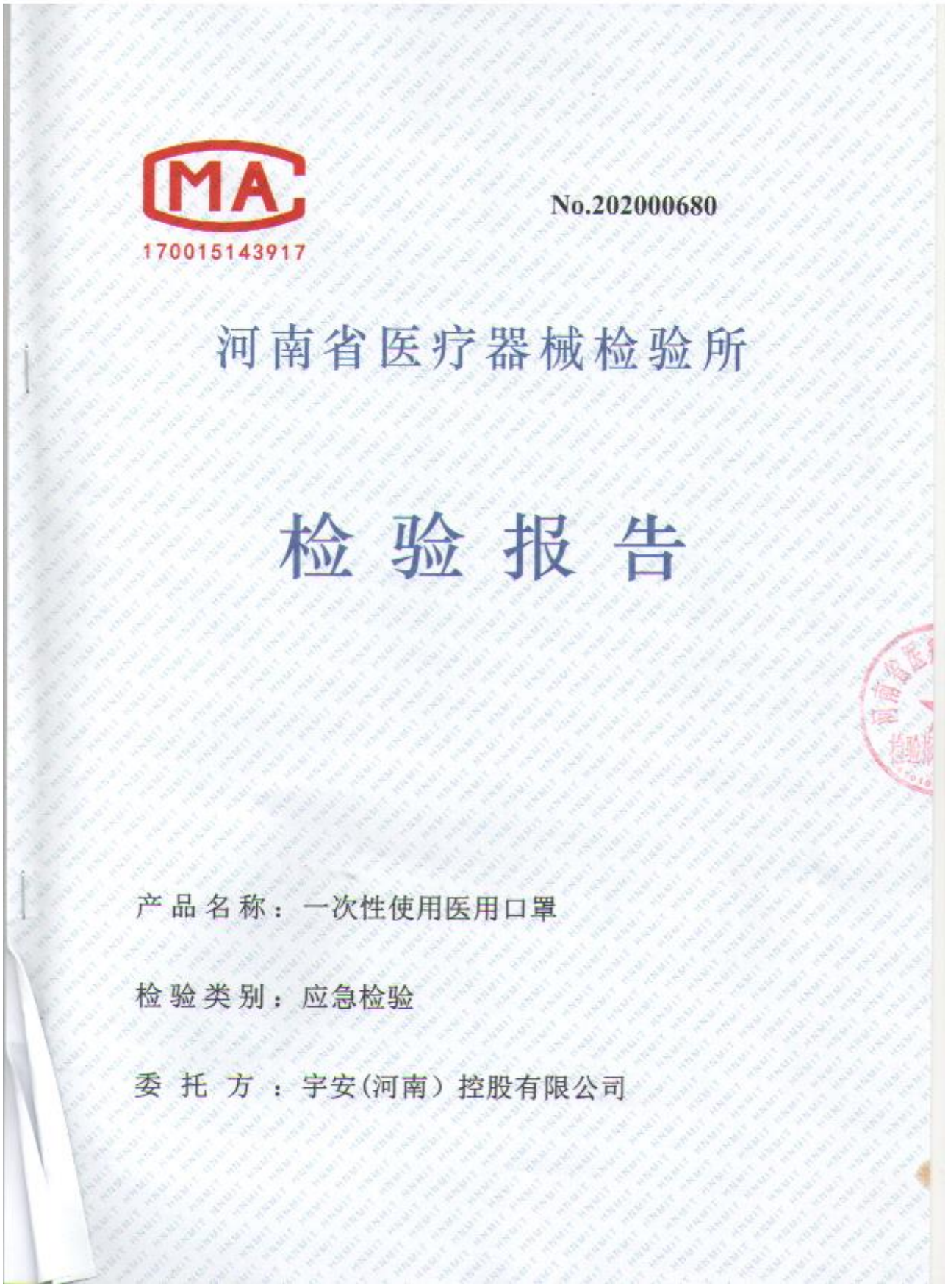
审批部门：河南省药品监督管理局

批准日期：二〇二〇年三月九日

有效期至：二〇二一年三月八日

（审批部门盖章）

- 一次性使用医用口罩 省级检验报告



CMA
170015143917

No.202000680

河南省医疗器械检验所

检 验 报 告

产品名称：一次性使用医用口罩

检验类别：应急检验

委 托 方 ：宇安(河南）控股有限公司

- 一次性使用医用口罩 合格证样张

YUAN 宇安控股 YU'AN HOLDING | 产品合格证 CERTIFICATE OF CONFORMITY

产品名称 Product name	一次性使用医用口罩 Disposable Medical Face Mask
医疗器械生产许可证号 Medical Device Production License No.	豫药监械生产许20200216号/Henan Pharmaceutical Supervision Production License No.20200216
医疗器械注册证号 Medical Device Registration Certificate No.	豫械注准20202140676/Henan Pharmaceutical Supervision Standard 20202140676
执行标准 Executive Standard	YY/T 0969-2013 YY/T 0969-2013
型号 Model	挂耳型/Hanging Ear Type
规格 Specifications	175mm×95mm ±5% 175mm×95mm ±5%
数量 Quantity	50只/50 Masks
生产日期 Production Date	
生产批号 Production batch NO.	
检验日期 Inspection Date	
保质期 Quality Guarantee Period	2年/Two Years
检验员代号 Inspector Code	01

宇安（河南）控股有限公司 质检专用章

宇安（河南）控股有限公司
地址：中国·河南省新乡市长垣市张三寨镇工业园168号
YU'AN (HENAN) HOLDING LIMITED COMPANY
No.168,Zhangsanzhai Town Industrial Park,Changyuan City,
Henan Province,China

- 宇安控股医用口罩 EN14683 检测报告

Report No.: BG2003TR9184S06 - Page 1 of 17 -

BORY

TEST REPORT

EN 14683:2019

Medical face masks - Requirements and test methods

Report Number.....:	BG2003TR9184S06
Tested by (+ signature) .....:	Roi Wei
Compiled by (+ signature) .....:	Jack Chen
Approved by (+ signature) .....:	Levi Hou
Date of issue.....:	Mar. 20, 2020
Total number of pages.....:	17 pages
Testing Laboratory .....:	Shenzhen Bory Technology Service Co., Ltd GuangZhou Branch
Address .....:	25F, Building 31, Changfeng International Zone, Xintang, Zengcheng District, Guangzhou
Address .....:	As above
Applicant's name .....:	Yu An (Henan) Holding Limited Company
Address .....:	No. 168, Industrial Park, ZhangSanZhai Town, ChangYuan City, XinXiang City, HeNan Province
Test specification:	
Standard.....:	EN 14683:2019
Test procedure.....:	CE
Non-standard test method.....:	N/A
Test Report Form No.....:	EN 14683: 2019
Test Report Form(s) Originator .....:	BORY
Master TRF.....:	Dated 2020-02
The test results presented in this report relate only to the object tested. This report shall not be reproduced except in full, without the written approval of the Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the Laboratory, responsible for this Test Report.	
Test item description.....:	Disposable Medical Mask
Trade Mark .....:	
Manufacturer .....:	Yang Ling Ao Rui Medical Devices Co., Ltd
Address .....:	C5, Free Trade Street, Yangling Demonstration Zone, ShanXi Province, China.
Model/Type reference .....:	I(clinical), II(surgical)

This Test Report is issued by the Company subject to its General Conditions of Service printed overleaf. Attention is drawn to the limitations of liability, indemnification and jurisdictional policies defined therein. The results shown in this test report refer only to the sample(s) tested unless otherwise stated and the sample(s) are retained for 30 days only.

List of Attachments (including a total number of pages in each attachment):
-- Attachment 1: One pages for Photo documentation.
Summary of testing:

Tests performed (name of test and test clause):	Testing location:
-- EN 14683:2019 Medical face masks - Requirements and test methods	25F, Building 31, Changfeng International Zone, Xintang, Zengcheng District, Guangzhou

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

(Additional requirements for markings. See 1.7 NOTE)

Disposable Medical Mask

I（clinical）

EN 14683: 2019

CE

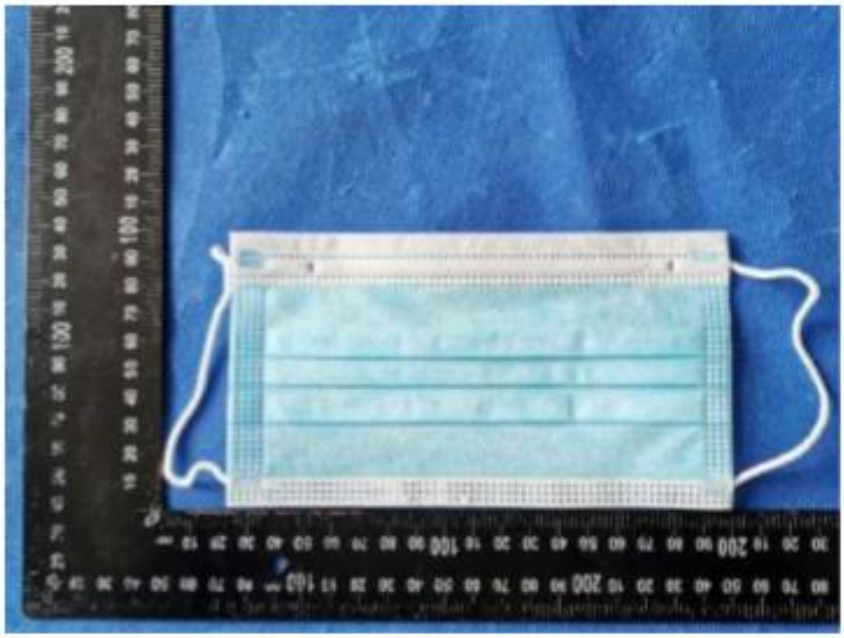
Type I

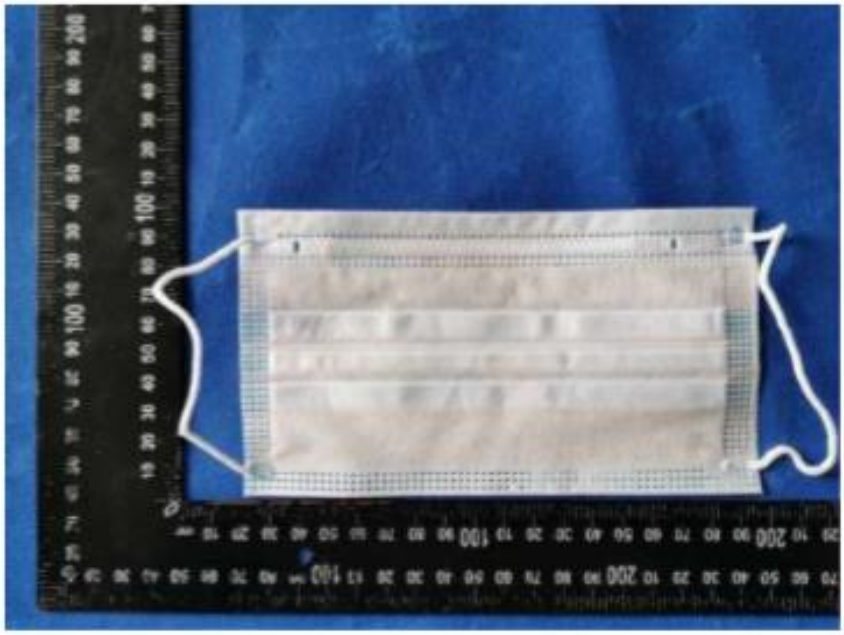
Possible test case verdicts:
- test case does not apply to the test object.....: N/A(or N)
- test object does meet the requirement .....: P (Pass)
- test object does not meet the requirement.....: F (Fail)
Testing.....:
Date of receipt of test item.....: Feb. 21, 2020
Date (s) of performance of tests.....: Feb. 21, 2020 – Mar.20, 2020
General remarks:
Throughout this report a ☒ comma / ☐ point is used as the decimal separator.
General product information: The product is intended to be used as medical face masks intended to lirrit the transmission of infective agents from staff to patients during: surgical procedures and other medical settings with similar requirements.

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
	Test specimens are complete masks or shall be cut from masks.	Complete mask.	P
	Each specimen shall be able to provide 5 different circular test areas of 2,5 cm in diameter.	Diameter: 2,5 cm	P
	If one specimen cannot provide 5 test areas of 2,5 cm in diameter, the number of test areas retrieved should be representative for the entire mask.	Diameter: 2,5 cm	P
	The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL of 4 %.	5 specimens	P
	All specimens tested shall be taken from areas representative from the mask to incorporate all/any variation in construction.		P
	Each test specimen shall be conditioned at (21 ±5) ℃ and (85 ±5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.	(21 ±2) ℃; (85 ±2) %	P
C.4	Procedure		P
C.4.1	The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm2) and clamped into place so as to minimise air leaks and that the tested area of the specimen will be in line and across the flow of air.	Area: 4,9 cm2	P
C.4.2	The pump is started and the flow of air adjusted to 8 l/min.		P
C.4.3	The manometers M1 and M2 are read and recorded.		P
C.4.4	The procedure described in steps C.4.1 through C.4.3 is carried out on 5 (or appropriate number of) different areas of the mask and the readings averaged.		P
C.5	Calculation of differential pressure		P
	For each test specimen calculate the differential pressure ΔP as.	ΔP = (Xm1 – Xm2)/4,9	P
C.6	Test report	a number and date of this European Standard; b lot number or batch code of the masks tested; c flow rate during testing; d differential pressure for each test specimen.	P

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
ZA	Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices		P
	This European Standard has been prepared under a mandate given to CEN by the European Commission Union to provide a means of conforming to the essential requirements of New Approach EU Directive 93/42/EEC concerning medical devices.		P
	Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.		P
ZA.1	Correspondence between this European Standard and EU Directive 93/42/EEC concerning medical devices		P
	Clause/subclause of this European Standard; 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.2.3, 6.....	Corresponding Essential Requirement of Directive 93/42/EEC: 8.1	P
	Clause/subclause of this European Standard; 5.2.2....	Corresponding Essential Requirement of Directive 93/42/EEC: 9.2	P
	Clause/subclause of this European Standard; 6.	Corresponding Essential Requirement of Directive 93/42/EEC: 13	P
	WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.		P
	WARNING 2 —Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.		P

Photo-documentation





========== End of test report==========

- 一次性使用医用口罩符合性声明

EC Declaration of Conformity

Manufacturer:

Yu an (Henan) Holding Limited Company
No. 168, Industrial Park, zhangsanzhai Town,
Changyuan City, Xinxiang City, Henan
Province,China

whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Disposable Medical Mask

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Yu an (Henan) Holding Limited Company
No. 168, Industrial Park, zhangsanzhai Town, Changyuan City, Xinxiang City, Henan Province,China

Place, date

Changyuan City
May 6, 2020

Legally binding signature, Function

Jiang Guangshong
GM.

EC Declaration of Conformity

Page 1/1

- 医用外科口罩 医疗器械注册证

中华人民共和国医疗器械注册证

注册证编号：豫械注准 20202140677

注册人名称	宇安（河南）控股有限公司
注册人住所	河南省新乡市长垣市张三寨镇工业园 168 号
生产地址	河南省新乡市长垣市张三寨镇工业园 168 号
代理人名称	不适用
代理人住所	不适用
产品名称	医用外科口罩
型号、规格	型号：挂耳型、系带型 规格：175mm×95mm、175mm×90mm、140mm×90mm
结构及组成	产品分三层，外层由纺粘非织造布构成，中间层由聚丙烯熔喷布构成，另配有鼻夹、口罩带。
适用范围	用于戴在手术室医务人员口鼻部位，以防止皮屑、呼吸道微生物传播到开放的手术创面，并阻止手术病人的体液向医务人员传播，起到双向生物防护的作用。
附　件	产品技术要求
其他内容	无
备　注	

审批部门：河南省药品监督管理局

批准日期：二〇二〇年三月三十日
有效期至：二〇二一年三月二十九日
（审批部门盖章）

- 医用一次性防护服 医疗器械注册证

中华人民共和国医疗器械注册证

注册证编号：豫械注准 20202140678

注册人名称	宇安（河南）控股有限公司
注册人住所	河南省新乡市长垣市张三寨镇工业园 168 号
生产地址	河南省新乡市长垣市张三寨镇工业园 168 号
代理人名称	不适用
代理人住所	不适用
产品名称	医用一次性防护服
型号、规格	型号：连身式、分身式 规格：160cm、165cm、170cm、175cm、180cm、185cm
结构及组成	防护服由帽子、上衣、裤子组成。
适用范围	用于医疗机构医护人员穿的职业防护衣，阻止来自患者的病毒随空气或者液体向医务人员传播。
附　件	产品技术要求
其他内容	无
备　注	

审批部门：河南省药品监督管理局

批准日期：二〇二〇年四月十五日
有效期至：二〇二五年四月十四日
（审批部门盖章）

- 宇安控股工厂厂区图


YUAN
宇安(河南)控股有限公司
YU'AN(HENAN) HOLDING LIMITED COMPANY


YUAN
宇安控股YU'AN HOLDING

- 医用一次性防护服 符合性说明

EC Declaration of conformity

2016/425 Personal protective equipment (PPE)

We,
Yu an (Henan) Holding Limited Company
No. 168, Industrial Park, Zhangsanzhai Town, Changyuan City, Xinxiang City, Henan Province , China

Product Name: Disposable Medical Protective Clothing
Product Model: 160, 165, 170, 175, 180, 185

The product has been assessed by the application of the following standards
PPF:
EN 14126:2003+AC:2004, EN ISO 13982 -1:2004+A1:2010

Issue place and date

Changyuan City
May 6, 2020

Company stamp and Signature of authorized personnel

Jiang Guangsheng
GM