YU'AN HOLDING

宇 安 控 股

产品 & 资质

PRODUCT & QUALIFICATION

STERILE
Aseptic

STERILE EO
Ethylene oxide sterilization

One-time use

CE

Precision Manufacturing

Four level filtering | Medical products | Lamination design | Comfortable and breathable | Good quality

用科技呵护生命！

Technology Saves Life!

YUAN 宇安(河南)控股有限公司

YU'AN(HENAN) HOLDING LIMITED COMPANY

全球防疫物资采购工厂·海外直供

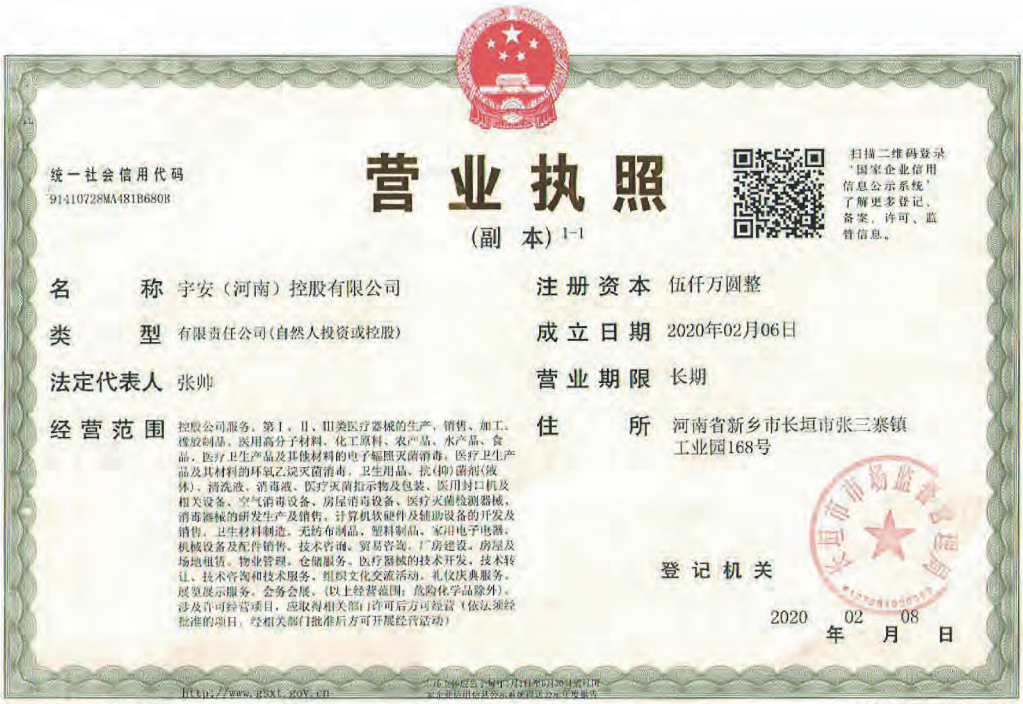
CHINA'S LEADING OVERSEAS SUPPLIER OF ANTI-EPIDEMIC MATERIALS

精工智造

CE

本企业产品已通过欧盟CE认证

目 录/CONTENTS



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　张帅
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。(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　2020 年 02 月 08 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

国家市场监督管理总局监制

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 09 日

国家食品药品监督管理总局制

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

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。

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

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）：

河南省药品监督管理局

2020年03月30日

1.2.156.3005.2.11410000MB1912677J037.11410000MB1912669P.4100002020000166.001.Z

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

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

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

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 aplying with the required standards

Certificate No. CE2020508-2

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

中国商品条码系统成员证书

GS1 China Membership License

物编注字第 号

Certificate No. 845437

成员名称：
Prefix Licensee's Name

注册地址：
Registration Address

河南省新乡市长垣市张三寨镇工业园168号

QR码　汉信码

厂商识别代码：697311437
GS1 Company Prefix（GCP）

厂商识别代码可用于生成下述标识代码：
GS1 Company Prefix is used to create the following GS1 Identification Keys

全球贸易项目代码（GTIN）	全球位置码（GLN）	系列货运包装箱代码（SSCC）	全球型号代码（GMN）
全球可回收资产代码（GRAI）	全球单个资产代码（GIAI）	全球服务关系代码（GSRN）	全球文件类型代码（GDTI）
全球货物托运标识代码（GINC）	全球货物装运标识代码（GSIN）		

持有本证书的成员对厂商识别代码及上述标识代码享有专用权。
The GS1 Company Prefix and other ID keys shown above are licensed for the sole use of the member named on this certificate.

机构全球位置码：6973114370014
Legal Entity Global Location Number (GLN)

有效期：2020年03月09日 至 2022年03月09日
This License shall become effective as of 09/03/2020 (d/m/y) and remain valid until 09/03/2022 (d/m/y).

NO. 0150658

GS1 China 中国物品编码中心

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, Zhangsanzhai Town, Changyuan City, Xinxiang City, Henan Province

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

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	

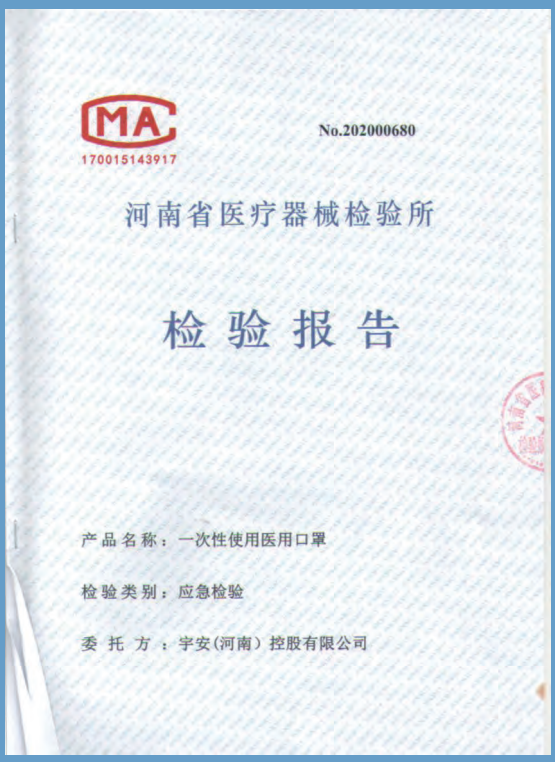
审批部门：河南省药品监督管理局

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）

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province



CMA
170015143917

No.202000680

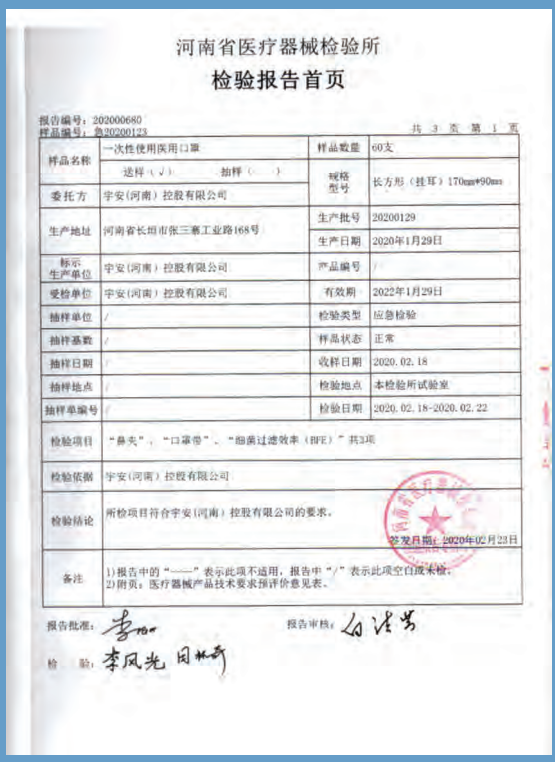
河南省医疗器械检验所

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



河南省医疗器械检验所

检验报告首页

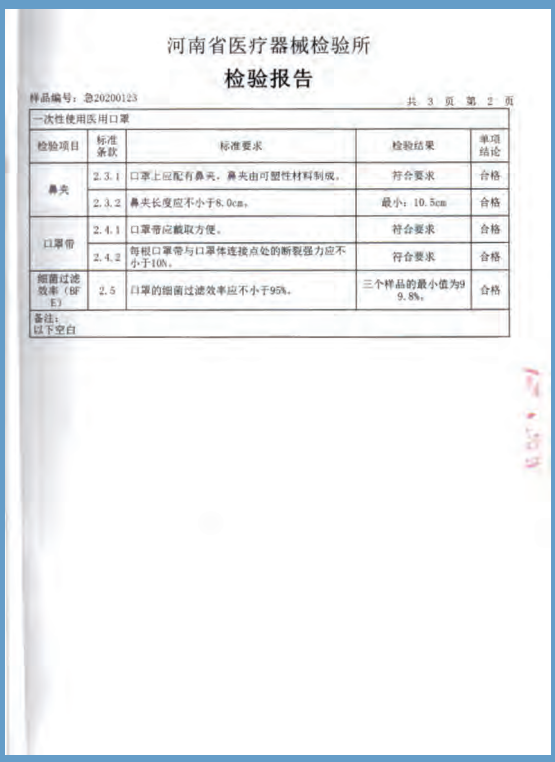
报告编号：202000680　　共 3 页 第 1 页
样品编号：急20200123

样品名称	一次性使用医用口罩	样品数量	60支
	送样（√） 抽样（ ）	规格型号	长方形（挂耳）170mm*90mm
委托方	宇安(河南）控股有限公司		
生产地址	河南省长垣市张三寨工业路168号	生产批号	20200129
		生产日期	2020年1月29日
标示生产单位	宇安(河南）控股有限公司	产品编号	/
受检单位	宇安(河南）控股有限公司	有效期	2022年1月29日
抽样单位	/	检验类型	应急检验
抽样基数	/	样品状态	正常
抽样日期	/	收样日期	2020.02.18
抽样地点	/	检验地点	本检验所试验室
抽样单编号	/	检验日期	2020.02.18-2020.02.22
检验项目	“鼻夹”、“口罩带”、“细菌过滤效率（BFE）”共3项		
检验依据	宇安(河南）控股有限公司		
检验结论	所检项目符合宇安(河南）控股有限公司的要求。		
备注	1)报告中的“——”表示此项不适用，报告中“/”表示此项空白或未检； 2)附页：医疗器械产品技术要求预评价意见表。		

签发日期：2020年02月23日

报告批准：　　报告审核：

检　验：李凤光 田林新



河南省医疗器械检验所

检验报告

样品编号：急20200123　　共 3 页 第 2 页

一次性使用医用口罩				
检验项目	标准条款	标准要求	检验结果	单项结论
鼻夹	2.3.1	口罩上应配有鼻夹，鼻夹由可塑性材料制成。	符合要求	合格
	2.3.2	鼻夹长度应不小于8.0cm。	最小：10.5cm	合格
口罩带	2.4.1	口罩带应截取方便。	符合要求	合格
	2.4.2	每根口罩带与口罩体连接点处的断裂强力应不小于10N。	符合要求	合格
细菌过滤效率（BFE）	2.5	口罩的细菌过滤效率应不小于95%。	三个样品的最小值为99.8%。	合格
备注：以下空白				

河南省医疗器械检验所

检验报告照片页

样品编号：急20200123　　共 3 页 第 3 页

照片说明

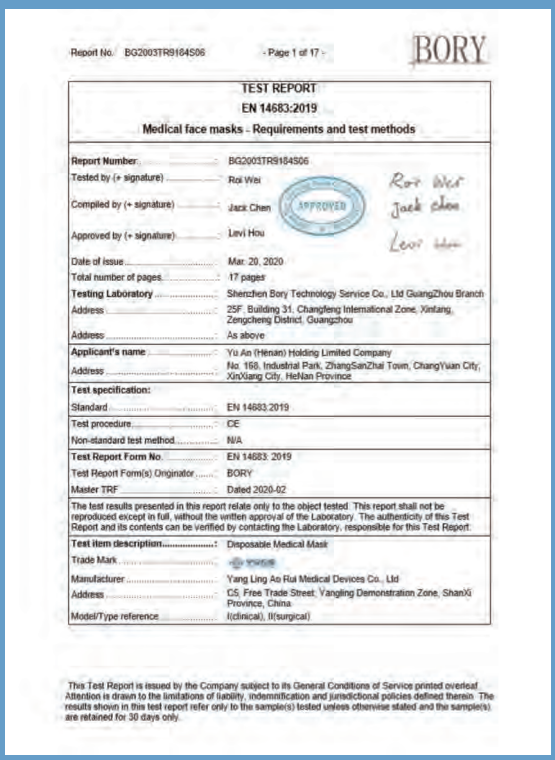
样品描述

/

型号规格或其他说明

产品标示型号规格：长方形（挂耳）170mm*90mm

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province



Report No.: BG2003TR9184S06 - Page 1 of 17 - BORY

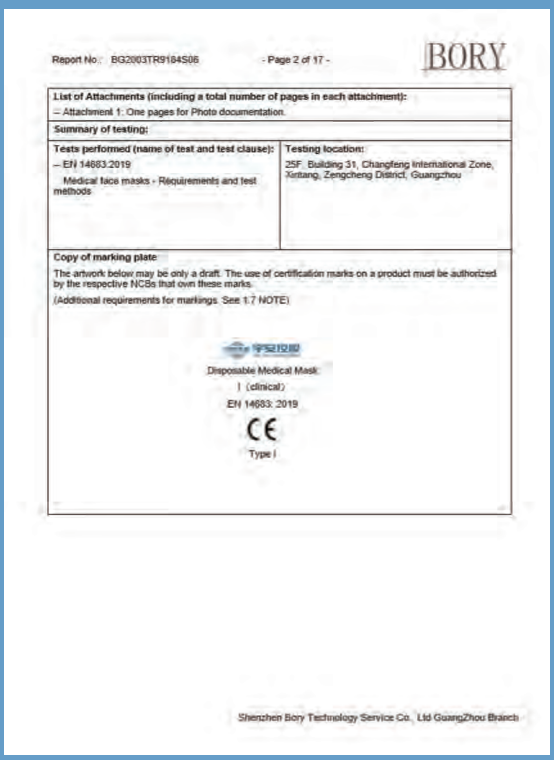
TEST REPORT
EN 14683:2019
Medical face masks - Requirements and test methods

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.



Report No.: BG2003TR9184S06 - Page 2 of 17 - BORY

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

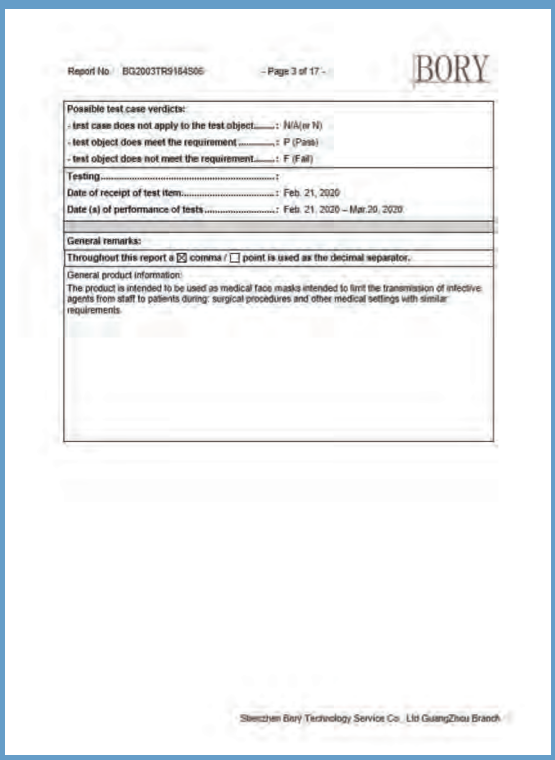
Copy of marking plate:

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 7.7 NOTE)

Disposable Medical Mask
I (clinical)
EN 14683: 2019
CE
Type I

Shenzhen Bory Technology Service Co., Ltd GuangZhou Branch



Report No.: BG2003TR9184S06 - Page 3 of 17 - BORY

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

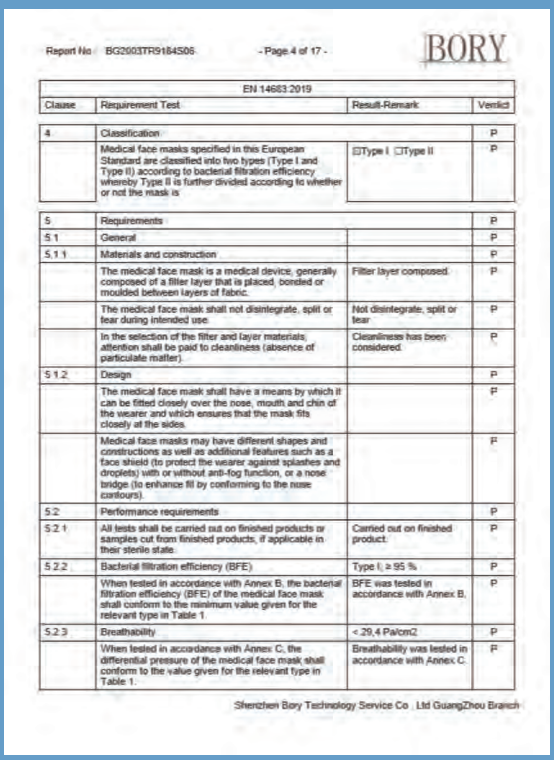
General remarks:

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 limit the transmission of infective agents from staff to patients during: surgical procedures and other medical settings with similar requirements.

Shenzhen Bory Technology Service Co., Ltd GuangZhou Branch



Report No.: BG2003TR9184S06 - Page 4 of 17 - BORY

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
4	Classification		P
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is	☑Type I ☐Type II	P
5	Requirements		P
5.1	General		P
5.1.1	Materials and construction		P
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	Filter layer composed.	P
	The medical face mask shall not disintegrate, split or tear during intended use.	Not disintegrate, split or tear	P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness (absence of particulate matter).	Cleanliness has been considered.	P
5.1.2	Design		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		P
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).		P
5.2	Performance requirements		P
5.2.1	All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.	Carried out on finished product.	P
5.2.2	Bacterial filtration efficiency (BFE)	Type I, ≥ 95 %	P
	When tested in accordance with Annex B, the bacterial filtration efficiency (BFE) of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	BFE was tested in accordance with Annex B.	P
5.2.3	Breathability	< 29,4 Pa/cm2	P
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	Breathability was tested in accordance with Annex C.	P

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Xinxiang City, Henan Province

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
5.2.4	Splash resistance	Not required.	N/A
	When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1		N/A
5.2.5	Microbial cleanliness (Bioburden)	≤ 30 cfu/g	P
	When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested.	Bioburden was tested according to EN ISO 11737- 1.	P
	EN ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation of the population of viable microorganisms on or in a medical device, component, raw material or package.		P
	To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below:		P
	□ The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.	5 specimens	P
	Weigh each mask prior testing.	Weights were recorded	P
	The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl & 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]).	Extraction liquid: 300 ml	P
	The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm	Shaken: 250 rpm	P
	After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µ filter and laid down on a TSA plate for the total viable aerobic microbial count.	Filter: 0,45 µ	P
	Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration.		P
	The plates are incubated for 3 days at 30 °C and 7 days at (20 – 25) °C for TSA and SDA plates respectively.	30 °C: 3 days; 20 °C– 25 °C: 7 days	P
	The total bioburden is expressed by addition of the TSA and SDA counts.		P
	In the report, indicate the total bioburden per mask and based on the mask weigh, the total bioburden per gram tested.		P

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
5.2.6	Biocompatibility	In accordance with EN ISO 10993-1.	P
	According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact.		P
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine the applicable toxicology testing regime.	In accordance with EN ISO 10993-1.	P
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		P
	The test results shall be available upon request.		P
	As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered. 5.2.7 Summary of performance requirements		P
5.2.7	Summary of performance requirements	a Bacterial filtration efficiency (BFE): ≥ 95%; b Differential pressure: < 29,4 Pa/cm2 ; c Splash resistance pressure: Not required; d Microbial cleanliness: ≤ 30 cfu/g.	P

Table 1 - Performance requirements for medical face masks			
Test	Type Ia	Type II	Type IIR
Bacterial filtration efficiency (BFE) (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm2)	< 29,4	< 29.4	< 49.0
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.

Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

6	Labelling and information to be supplied		P
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) specifies the information that has to be specified on the packaging in which the medical face mask is supplied.		P

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
	The following information shall be supplied in addition:		P
	a) ... umber of this European Standard	EN 14683:2019	P
	b) ... type of mask (as indicated in Table 1).	Type I	P
	EN ISO 15223-1 and EN 1041 should be considered.		P
6	Information for users		P
	When breathing, speaking, coughing, sneezing etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose.		P
	The majority of the nuclei are between 0,5 µm and 12 µm in diameter and especially the larger droplets can contain micro-organisms from the source site.	Nuclei: 0,5 µm - 12 µm.	P
	Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.		P
	The medical face masks intended to be used in operating rooms and health care settings with similar requirements are designed to protect the entire working environment.	It was designed to protect the entire working environment	P
	This standard describes two types of medical face masks with associated protection levels.	Type I medical face mask.	P
	As a minimum, Type I medical face masks are used for patients in order to reduce the risk of the spread of infections, particularly in epidemic or pandemic situations.		P
	Type II masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements.	Type I medical face mask	N/A
	A special case, also covered by the European Medical Devices legislation, is that in which the wearer wishes to protect him/herself against splashes of potentially contaminated fluids and particles that are created in the surgical environment, e.g. by the use of electro-cautery devices.		P
	If the intended use of the mask is to protect the wearer against infective agents (bacteria, viruses or fungi), the use of a respirator device should be considered.		N/A
	Performance requirements for respirators are the scope of EN 149.	In accordance with EN 149.	P
	The level of efficiency offered by a mask depends on a number of factors such as the filtration efficiency, quality of the material and the fit of the mask on the wearer's face.		P

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
	Different designs are suited for different applications and the careful choice of mask is therefore important in order to achieve the desired result.		P
	The filtration capacity of mask materials can vary depending on the filter media.		P
	The fit of masks varies considerably from those which are held in place by ear loops fastened behind the wearer's ears to those with tie bands around the head and a nose clamp that can be shaped to the wearer's nose.	Can be shaped to the wearer's nose.	P
	The effect of a very good or less good fit can be tested in vivo whereas the filtration efficiency may be reproducibly tested in vitro.	Effect can be tested in vivo	P
	The considerable variations in results when masks are tested in vivo results in the need for large groups of test subjects and observations.	No any variations.	N/A
	It is thus usual to characterise mask performance using in vitro tests of the material from which the mask is made.		P
	It is, however, important to consider the fit of the mask carefully when a mask for a certain application is chosen. Users should request such information from their suppliers.		P
	A further factor to be considered is the capacity of the mask to absorb moisture from the exhaled air and thereby to maintain its performance over a longer period of time.		P
	The more advanced designs easily maintain their performance throughout even very long operations whereas the less advanced ones are intended only for short procedures.		P
	The contamination risk resulting from hand contact with a used mask means that it is essential that the mask is taken off and disposed of when no longer worn over nose and mouth.	No longer worn over nose and mouth.	P
	When there is a further need for protection then a new mask should be put on.	No further need for protection.	N/A
	Touching a used face mask or putting on a new one should always be followed by a full hand disinfection procedure and a used mask should always be disposed of when no longer needed or between two procedures.		P
	In summary, to use an appropriate mask is an effective means to protect the working environment from droplet contamination from nose and throat during health care procedures.		P

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
	Masks with very different performance are, however, available.	Without very different performance	N/A
	Therefore such factors as infection risk and mask fit should be carefully considered when choosing a mask.		P
B	Method for in-vitro determination of bacterial filtration efficiency (BFE)		P
	WARNING		P
	□ ... Staphylococcus aureus is a pathogen		P
	□ ... The relevant national provisions by law and hygienic instructions when dealing with pathogens shall be complied with		P
B.1	Principle		P
	A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber		P
	An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum		P
	The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol		P
B.2	Reagents and materials		P
B.2.1	General		P
	B.2.2 and B.2.3 describe commercially available solutions of tryptic soy agar and tryptic soy broth		P
	Other variants may be suitable		P
B.2.2	Tryptic soy agar		P
	Formula/liter:		P
	□ ... Enzymatic digest of casein	15g	P
	□ ... Enzymatic digest of soybean meal	5g	P
	□ ... Sodium chloride	5g	P
	□ ... Agar	15g	P
	□ ... Final pH	7.3 ±0.2 at 23°C	P
B.2.3	Tryptic soy broth		P
	Formula/liter:		P
	□ ... Enzymatic digest of casein	17g	P
	□ ... Enzymatic digest of soybean meal	3g	P

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
	□ ... Sodium chloride	5g	P
	□ ... Dipotassium phosphate	2.5g	P
	□ ... Dextrose	2.5g	P
	□ ... Final pH	7.3 ±0.2 at 25°C	P
B.2.4	Peptone water		P
	Formula/litre:		P
	□ ... Peptone	10g	P
	□ ... Sodium chloride	5g	P
	□ ... Final pH	7.2 ±0.2 at 25°C	P
B.2.5	Culture of Staphylococcus aureus ATCC 6538 growing on tryptic soy agar slants		P
B.3	Apparatus		P
B.3.1	Six stage cascade impactor		P
B.3.2	Nebulizer, capable of delivering particles with a mean size of (3,0 ± 0,3) µm when in contact with the impactor	3 I µm	P
B.3.3	Aerosol chamber, glass, 600 mm long and 80 mm in external diameter	Long: 600 mm Diameter: 80 mm	P
B.3.4	Flow meters, capable of measuring a flow rate of 28,3 l/min	Flow rate: 28.3 l/min	P
B.3.5	Pressure gauge, capable of measuring a pressure of 35 kPa to an accuracy of ± 1 kPa	35 kPa	P
B.3.6	Erlenmeyer flasks, 250 ml and 500 ml capacity		P
B.3.7	Peristaltic or syringe pump, capable of delivering 0,01 ml/min		P
B.3.8	Vacuum pump, capable of maintaining a flow rate of 57 l/min	Flow rate: 57 l/min	P
B.4	Test apparatus		P
B.4.1	**Six stage cascade impactor,** the arrangement is specified in Table B.1		P
B.4.2	**Nebulizer,** capable of delivering particles with a mean size of (3,0 ± 0,3) µm when in contact with the cascade impactor		P
B.4.3	**Aerosol chamber,** glass, 600 mm long and 80 mm in external diameter		P
B.4.4	**Flow meters,** capable of measuring a flow rate of 28,3 l/min		P
B.4.5	**Pressure gauge,** capable of measuring a pressure of 35 kPa to an accuracy of ± 1 kPa		P

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
B.4.6	**Erlenmeyer flasks,** 250 ml and 500 ml capacity		P
B.4.7	**Peristaltic or syringe pump,** capable of delivering 0,01 ml/min		P
B.4.7	**Vacuum pump,** capable of maintaining a flow rate of 57 l/min.		P
B.5	Test specimens		P
	Test specimens shall be cut from complete masks.		P
	Each specimen shall be minimum 100 mm by 100 mm and shall include all layers of the mask in the order in which they are placed in the complete mask.		P
	The number of specimens that shall be tested is minimum 5 (five), 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 representative areas to incorporate all any variation in construction.		P
	Unless otherwise specified, the testing shall be performed with the inside of the medical face mask in contact with the bacterial challenge.		P
	Each test specimen shall be conditioned at (21 ±5) °C and (85 ±5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.		P
B.6	Preparation of bacterial challenge	37 °C for 24 h	P
	Staphylococcus aureus (see B.2.4) shall be inoculated into 30 ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at a temperature of (37 ± 2) °C for (24 ±2) h.	5 × 10 5 cfu/ml	P
	The culture shall then be diluted in peptone water to give a concentration of approximately 5 × 10 5 cfu/ml	2300 cfu	P
	The bacterial challenge shall be maintained at 1,7 × 10^5 to 3,0 × 10^5 CFU per test.		P
	The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see B.7.3) and the dilution of the challenge suspension adjusted accordingly		P
	The mean particle size in the bacterial challenge shall be maintained at (3,0 ± 0,3) µm (see B.7.9).	3,1 µm	P
B.7	Procedure		P
B.7.1	Assemble the apparatus in accordance with the flow chart shown in Figure B.1		P

EN 14683:2019			
Clause	Requirement Test	Result-Remark	Verdict
B.7.2	Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.		P
B.7.3	Perform a positive control run without a test specimen. Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28,3 l/min.	Flow rate: 28,3 l/min.	P
	Deliver the bacterial challenge for 1 min.		P
	Maintain the airflow through the impactor for 2 min.	2 min	P
	Then remove the plates from the impactor.		P
	Ensure that each plate is numbered to indicate its position in the impactor.		P
B.7.4	Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.		P
B.7.5	Repeat this procedure for each test specimen		P
B.7.6	After the last test specimen has been tested, perform a further positive control run		P
B.7.7	Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.	2 min	P
B.7.8	Incubate all the plates at (37 ±2) °C for (20 to 52) h.	37 °C for 48 h	P
B.7.9	For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of cfu collected by the impactor using the "positive hole" conversion table(1) in accordance with the instructions of the cascade impactor manufacturer (stages 3 to 6).		P
	For the two positive control runs, take the mean of the two totals		P
	From the positive control plates calculate the mean particle size of the bacterial challenge aerosol using the "positive hole" conversion table in accordance with the instructions of the cascade impactor manufacturer.		P
B.8	Calculation of bacterial filtration efficiency		P
	For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the formula	B = (C − T) / C × 100 C is the mean of the total plate counts for the two positive control runs; T is the total plate count for the test specimen	P
B.9	Test report	a number and date of this European	P

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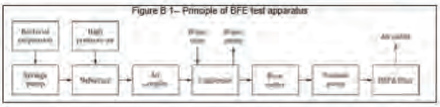
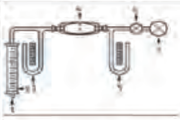
EN 14683:2019			
Clause	Requirement-Test	Result-Remark	Verdict
		Standard; b lot number or batch code of the masks tested; c dimensions of the test specimens and the size of the area tested; d which side of the test specimen was facing towards the challenge aerosol; e flow rate during testing; f mean of the total plate counts of the two positive controls; g mean plate count of the negative controls; h bacterial filtration efficiency for each test specimen.	

Figure B.1– Principle of BFE test apparatus



C	Method for determination of breathability (differential pressure		P
C.1	Principle		P
	A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure C.1.		P

EN 14683:2019			
Clause	Requirement-Test	Result-Remark	Verdict
			
	Water-filled manometers (M1 and M2) are used to measure the differential pressure.		P
	A flow meter is used for measurement of the airflow		P
	An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the airflow rate.		P
C.2	Apparatus		P
C2.1	Flow meter, capable of measuring an airflow of 8 l/min	Airflow: 8 l/min	P
C2.2	Manometers, M1 and M2 or differential manometer		P
C2.3	Electric vacuum pump including a pressure buffer tank		P
C2.4	Valve permitting the adjustment of the flow rate		P
C2.5	Sample holder		P
C2.5.1	The sample holder shall consist of a mechanical clamping system and alignment of the top and bottom holder.		P
C2.5.2	The sample holder shall consist of a mechanism to adjust the clamping pressure. A system with thread of screw can be used either at the bottom or top part of the sample holder.		P
C2.5.3	The internal diameter of the top holder and the bottom holder in the contact area with the filter material shall be (25 ± 1) mm.		P
C2.5.4	The seal of the top and bottom holder onto the filter material shall consist of a metal-metal contact.		P
C2.5.5	Validation of the test apparatus shall consist of a leak test. A second flow meter (12) placed immediately before the valve (10) will allow for evaluation of an air leak within the test apparatus. With the sample holder closed, start the pump and adjust the flow meter to read 8 l/min on the first flow meter (2). If no leaks are present both flow meters should read 8 l/min.		P
C.3	Test specimens		P

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) °C and (85 ±5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.	(21 ±2) °C; (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, 8.....	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

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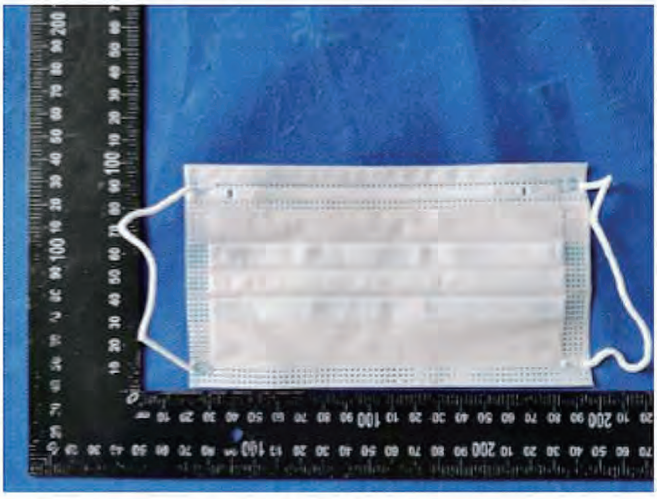
Photo-documentation



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

Shenzhen Bory Technology Service Co., Ltd GuangZhou Branch.

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 Guangshang

GM.

EC Declaration of Conformity

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一次性使用医用口罩纸塑袋

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

一次性使用医用口罩纸盒

一次性使用医用口罩小包装

儿童一次性使用医用口罩纸塑袋

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

YUAN 宇安控股 YU'AN HOLDING | 产品合格证 PRODUCT CERTIFICATION

产品名称 Product Name	一次性使用医用口罩 Disposable Medical 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/T0969-2013
型 号 Model	挂耳型/ Hanging Ear Type
规 格 Specifications	大号/ Large Size
产品成分 Product Ingredients	30%蓝色无纺布+30%熔喷布+40%白色无纺布 30% Blue Non-woven Fabric + 30% Melt-blown Fabric + 35% White Non-woven Fabric
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	
有 效 期 Valid Period	2年/ Two Years
检验员代号 Inspector Code	01

检验专用章

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

一次性使用医用口罩纸箱包装

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

一次性使用医用口罩出口纸盒

一次性使用医用口罩出口小包装

Yu'an (Henan) Holding Co., Ltd
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Xinxiang City, Henan Province

一次性使用医用口罩出口小包装

儿童一次性使用医用口罩_出口纸塑袋

一次性使用医用口罩出口纸箱

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

中华人民共和国医疗器械注册证

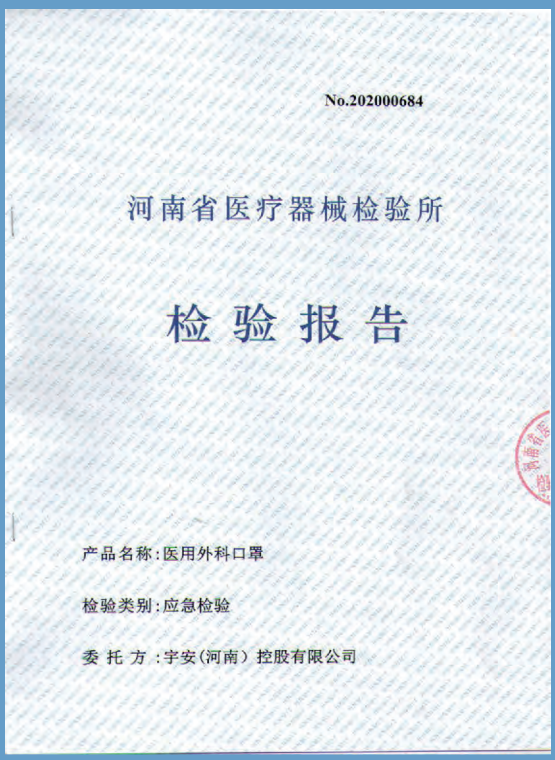
注册证编号：豫械注准 20202140677

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：二〇二〇年三月二十日
有效期至：二〇二一年三月二十九日
（审批部门盖章）

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province



No.202000684

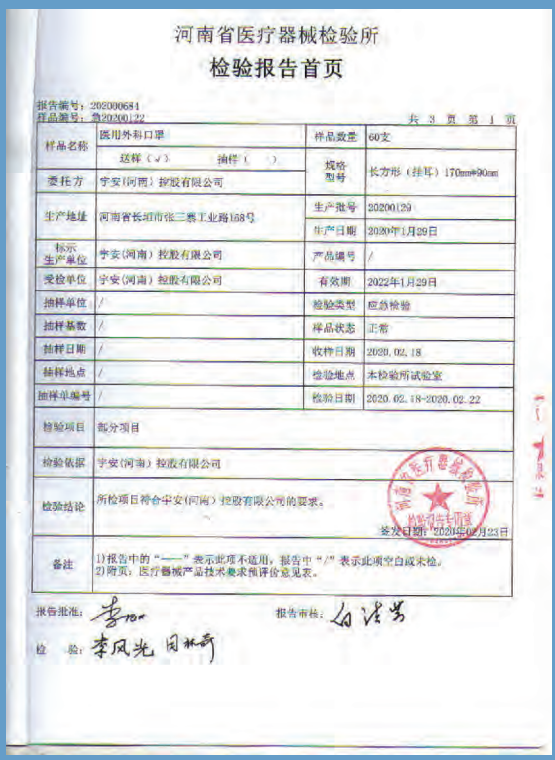
河南省医疗器械检验所

检 验 报 告

产品名称:医用外科口罩

检验类别:应急检验

委 托 方 :宇安(河南) 控股有限公司



河南省医疗器械检验所

检验报告首页

报告编号:202000684
样品编号:急20200122 共 3 页 第 1 页

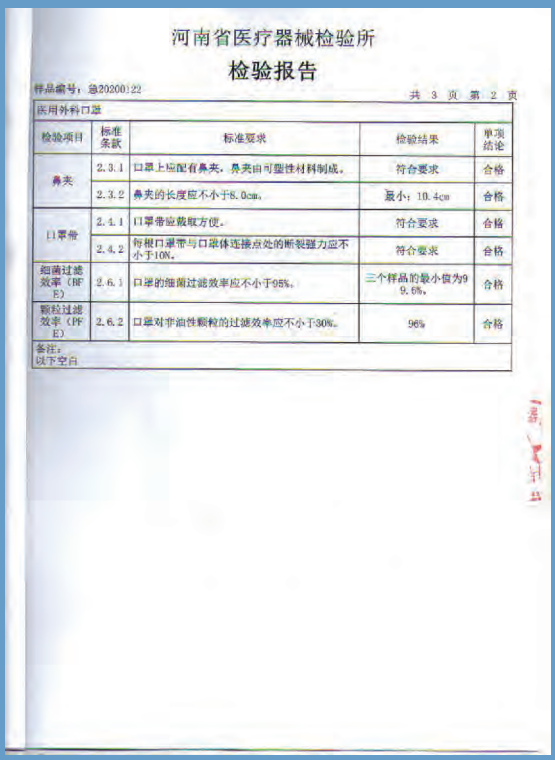
样品名称	医用外科口罩	样品数量	60支
	送样(√) 抽样( )	规格型号	长方形(挂耳) 170mm*90mm
委托方	宇安(河南)控股有限公司		
生产地址	河南省长垣市张三寨工业路168号	生产批号	20200129
		生产日期	2020年1月29日
标示生产单位	宇安(河南)控股有限公司	产品编号	/
受检单位	宇安(河南)控股有限公司	有效期	2022年1月29日
抽样单位	/	检验类型	应急检验
抽样基数	/	样品状态	正常
抽样日期	/	收样日期	2020.02.18
抽样地点	/	检验地点	本检验所试验室
抽样单编号	/	检验日期	2020.02.18-2020.02.22
检验项目	部分项目		
检验依据	宇安(河南)控股有限公司		
检验结论	所检项目符合宇安(河南)控股有限公司的要求。		
备注	1)报告中的"——"表示此项不适用,报告中"/"表示此项空白或未检。 2)附页:医疗器械产品技术要求预评价意见表。		

签发日期:2020年02月23日

报告批准:

报告审核:

检 验:李凤光 田林哥



河南省医疗器械检验所

检验报告

样品编号:急20200122 共 3 页 第 2 页

医用外科口罩

检验项目	标准条款	标准要求	检验结果	单项结论
鼻夹	2.3.1	口罩上应配有鼻夹,鼻夹由可塑性材料制成。	符合要求	合格
	2.3.2	鼻夹的长度应不小于8.0cm。	最小:10.4cm	合格
口罩带	2.4.1	口罩带应戴取方便。	符合要求	合格
	2.4.2	每根口罩带与口罩体连接点处的断裂强力应不小于10N。	符合要求	合格
细菌过滤效率(BFE)	2.6.1	口罩的细菌过滤效率应不小于95%。	三个样品的最小值为99.6%。	合格
颗粒过滤效率(PFE)	2.6.2	口罩对非油性颗粒的过滤效率应不小于30%。	96%	合格

备注:
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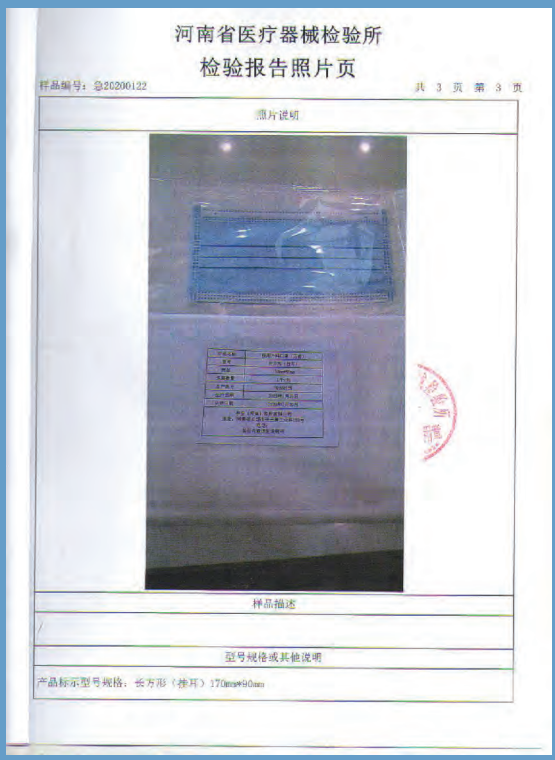


河南省医疗器械检验所

检验报告照片页

样品编号:急20200122 共 3 页 第 3 页

照片说明

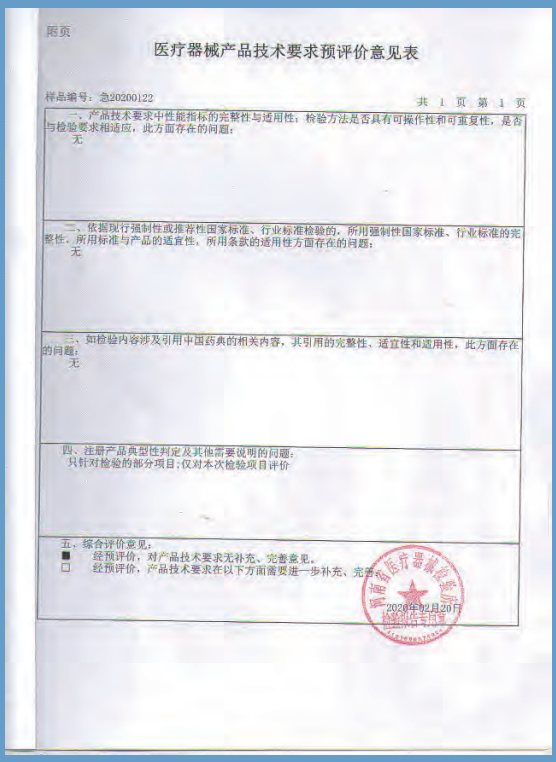
样品描述

/

型号规格或其他说明

产品标示型号规格:长方形(挂耳)170mm*90mm

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province



附页

医疗器械产品技术要求预评价意见表

样品编号：急202001122　　共 1 页 第 1 页

一、产品技术要求中性能指标的完整性与适用性，检验方法是否具有可操作性和可重复性，是否与检验要求相适应，此方面存在的问题：
无

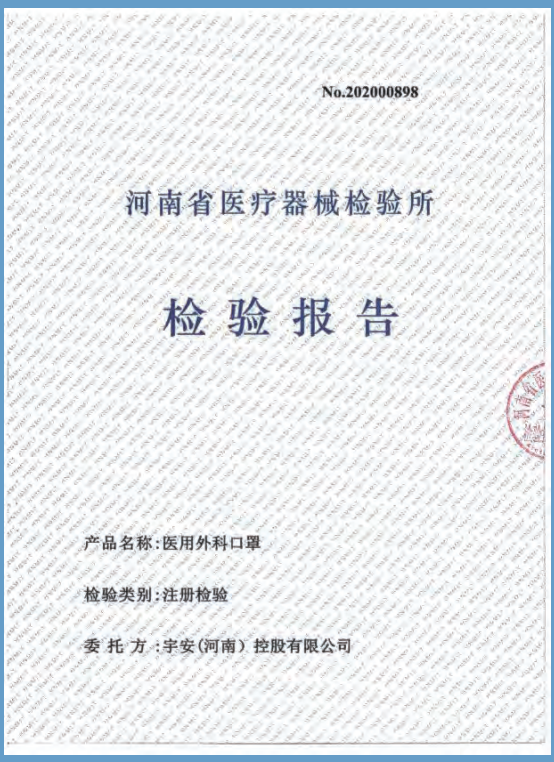
二、依据现行强制性或推荐性国家标准、行业标准检验的，所用强制性国家标准、行业标准的完整性、所用标准与产品的适宜性，所用条款的适用性方面存在的问题：
无

三、如检验内容涉及引用中国药典的相关内容，其引用的完整性、适宜性和适用性，此方面存在的问题：
无

四、注册产品典型性判定及其他需要说明的问题：
只针对检验的部分项目；仅对本次检验项目评价

五、综合评价意见：
■ 经预评价，对产品技术要求无补充、完善意见。
□ 经预评价，产品技术要求在以下方面需要进一步补充、完善：

2020年02月20日



No.202000898

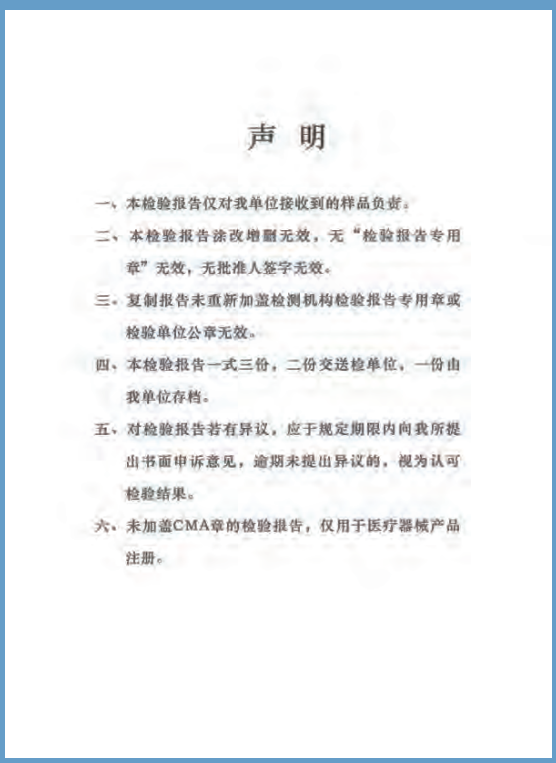
河南省医疗器械检验所

检 验 报 告

产品名称：医用外科口罩

检验类别：注册检验

委 托 方：宇安(河南) 控股有限公司



声 明

一、本检验报告仅对我单位接收到的样品负责。

二、本检验报告涂改增删无效，无“检验报告专用章”无效，无批准人签字无效。

三、复制报告未重新加盖检测机构检验报告专用章或检验单位公章无效。

四、本检验报告一式三份，二份交送检单位，一份由我单位存档。

五、对检验报告若有异议，应于规定期限内向我所提出书面申诉意见，逾期未提出异议的，视为认可检验结果。

六、未加盖CMA章的检验报告，仅用于医疗器械产品注册。

河南省医疗器械检验所

检验报告首页

报告编号：202000898
样品编号：急20200100　　共 3 页 第 1 页

样品名称	医用外科口罩	样品数量	60支
	送样（√）　抽样（　）	规格型号	长方形（挂耳）170mm*90mm
委托方	宇安(河南) 控股有限公司		
生产地址	河南省长垣市张三寨工业路168号	生产批号	20200129
		生产日期	2020年1月29日
标示生产单位	宇安(河南) 控股有限公司	产品编号	/
受检单位	宇安(河南) 控股有限公司	有效期	/
抽样单位	/	检验类型	注册检验
抽样基数	/	样品状态	正常
抽样日期	/	收样日期	2020.02.18
抽样地点	/	检验地点	本检验所试验室
抽样单编号	/	检验日期	2020.02.18~2020.02.28
检验项目	部分项目		
检验依据	宇安(河南) 控股有限公司《医用外科口罩》产品技术要求		
检验结论	所检项目符合宇安(河南) 控股有限公司《医用外科口罩》产品技术要求的要求。 签发日期：2020年03月02日		
备注	1)报告中的“——”表示此项不适用，报告中“/”表示此项空白或未检； 2)附页：医疗器械产品技术要求预评价意见表。		

报告批准：　　报告审核：

检　验：李凤光 闫林奇 刘向辉

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

附页

医疗器械产品技术要求预评价意见表

样品编号：注20200100　　共 1 页 第 1 页

一、产品技术要求中性能指标的完整性与适用性；检验方法是否具有可操作性和可重复性，是否与检验要求相适应。此方面存在的问题：
无

二、依据现行强制性或推荐性国家标准、行业标准检验的，所用强制性国家标准、行业标准的完整性，所用标准与产品的适宜性，所用条款的适用性方面存在的问题：
无

三、如按验内容涉及引用中国药典的相关内容，其引用的完整性、适宜性和适用性，此方面存在的问题：
无

四、注册产品典型性判定及其他需要说明的问题：
只针对检验的部分项目；仅对本次检验项目评价

五、综合评价意见：
■ 经预评价，对产品技术要求无补充、完善意见。
□ 经预评价，产品技术要求在以下方面需要进一步补充、完善：

2020年02月20日

河南省医疗器械检验所
检验报告

样品编号：注20200100　　共 3 页 第 2 页

医用外科口罩

检验项目	标准条款	标准要求	检验结果	单项结论
外观	2.1	口罩外观应整洁，形状完好，表面不得有破洞、污渍。	符合要求	合格
结构与尺寸	2.2	口罩佩戴好后，应能罩住佩戴者的鼻，口至下颌。尺寸及允差应符合表1	佩戴符合要求，技术要求中无此规格，尺寸无法检验	/
压力差(ΔP)	2.7	口罩两侧面进行气体交换的压力差ΔP应不大于49 Pa。	最大：37Pa	合格
阻燃性能	2.8	口罩材料应采用不易燃材料，口罩离开火焰后燃烧不大于5 s。	符合要求	合格
口罩应无菌	2.9.3	无菌口罩应无菌	无菌生长	合格
环氧乙烷残留量	2.1	口罩经环氧乙烷灭菌，其环氧乙烷残留量应不超过10ug/g。	未检出（检出限为0.05 μg/ml）	合格

备注：
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河南省医疗器械检验所
检验报告照片页

样品编号：注20200100　　共 3 页 第 3 页

照片说明

样品描述

/

型号规格或其他说明

产品标示型号规格：长方形（挂耳）170mm*90mm

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

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 Surgical 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

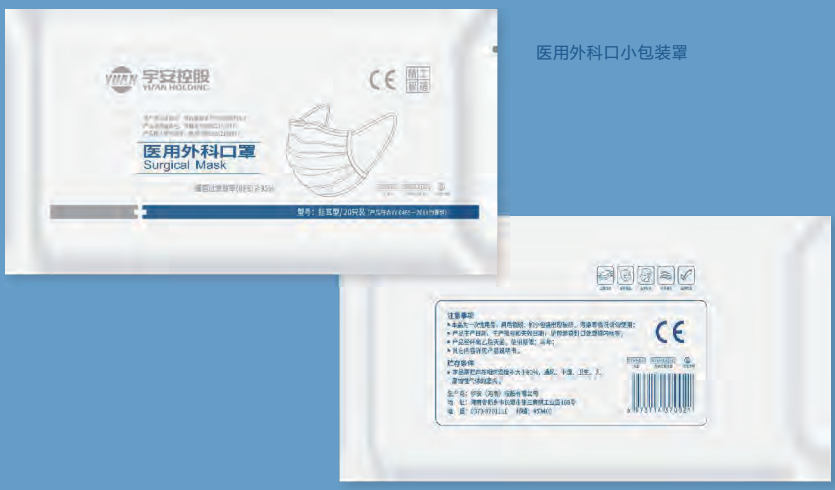
Legally binding signature, Function

Jiang Guangsheng

GM

EC Declaration of Conformity

Page 1/1



医用外科口小包装罩

儿童医用外科口罩纸塑袋

医用外科口罩纸箱

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

医用外科口罩小包装

儿童医用外科口罩纸塑袋

医用外科口罩纸箱

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

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）

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

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
PPE:
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

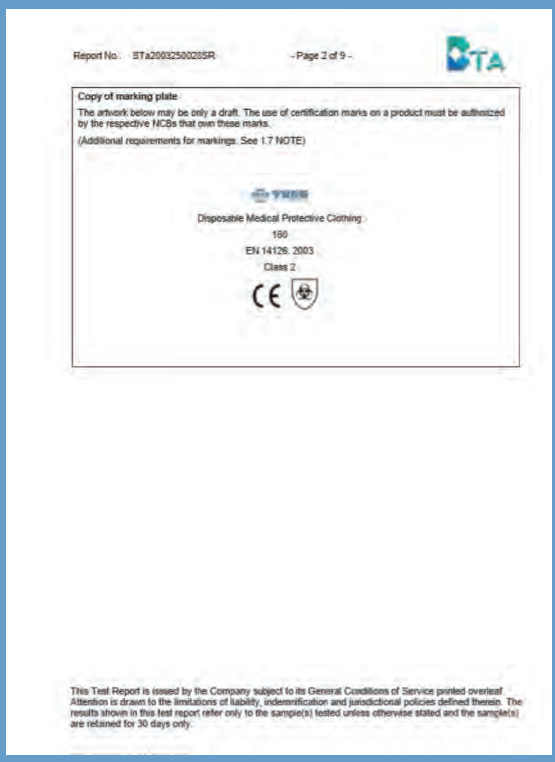
Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

Report No.: BTa2003250028SR - Page 1 of 9 -

TEST REPORT
EN 14126:2003
Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

Report Number	BTa2003250028SR
Tested by (+ signature)	Alice Luo
Compiled by (+ signature)	Jane Lin
Approved by (+ signature)	Jacky Wu
Date of issue	Mar. 25, 2020
Total number of pages	9 pages
Testing Laboratory	Shenzhen BTa Product Testing Co., Ltd.
Address	Room410, Floor 4, new tea village industrial park guofu community, Gixiang street,baoan district, Shenzhen China
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 14126: 2003
Test procedure	LVD Scheme
Non-standard test method	N/A
Test Report Form No.	EN 14126_V
Test Report Form(s) Originator	China Ceprei (Sichuan) Laboratory
Master TRF	Dated 2018-12
This European Standard specifies minimum requirements for filtering half masks as respiratory protective devices to protect against particles except for escape purposes. Laboration) and practical performance tests are included for The assessment of compliance with The requirements.	
Test item description	Disposable Medical Protective Clothing
Trade Mark:	
Manufacturer	Yu an (Henan) Holding Limited Company
Address	No. 168, Industrial Park, ZhangSanZhai Town, Changyuan City, XinXiang City, HeNan Province
Model/Type reference	160, 165, 170, 175, 180, 185
Ratings	—

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.



Report No.: BTa2003250028SR - Page 2 of 9 -

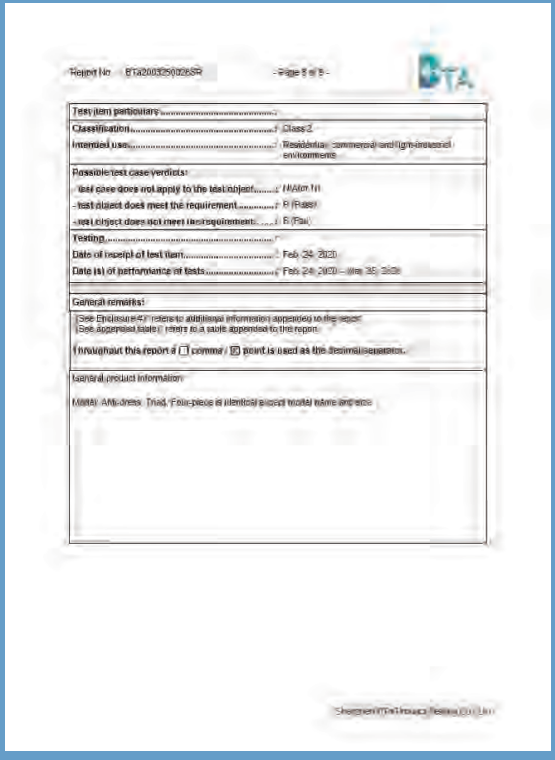
Copy of marking plate

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 Protective Clothing
160
EN 14126: 2003
Class 2

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.



Report No.: BTa2003250028SR - Page 3 of 9 -

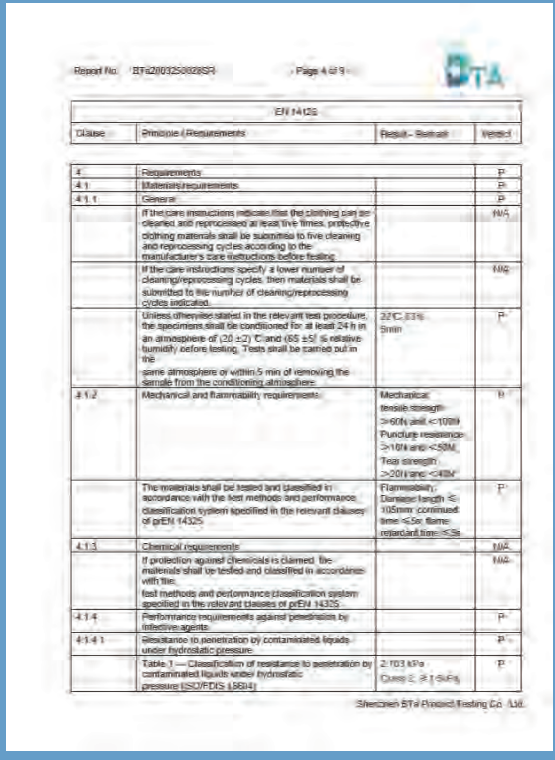
Test item particulars:	
Classification	Class 2
Intended use	Residential, commercial and light-industrial environments
Possible test case verdicts:	
- test case does not apply to the test object	N/A(or NI)
- test object does meet the requirement	P (Pass)
- test object does not meet the requirement	F (Fail)
Testing	
Date of receipt of test item	Feb. 24, 2020
Date (s) of performance of tests	Feb. 24, 2020 ~ Mar. 25, 2020

General remarks:

See Enclosure #2" refers to additional information appended to the report.
See appended table" refers to a table appended to the report.
Throughout this report a ☐ comma / ☑ point is used as the decimal separator.

General product information:

Model: Anti-dress, Triad, Four-piece is identical except model name and size.



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Clause	Requirement / Test	Result - Remark	Verdict
	EN 14126		
4	Requirements		P
4.1	Materials requirements		P
4.1.1	General		P
	If the care instructions indicate that the clothing can be cleaned, and reprocessed at least five times, protective clothing materials shall be submitted to five cleaning and reprocessing cycles according to the manufacturer's care instructions before testing.		N/A
	If the care instructions specify a lower number of cleaning/reprocessing cycles, then materials shall be submitted to this number of cleaning/reprocessing cycles indicated.		N/A
	Unless otherwise stated in the relevant test procedure, the specimens shall be conditioned for at least 24 h in an atmosphere of (20 ±2) °C and (65 ±5)' % relative humidity before testing. Tests shall be carried out in the same atmosphere or within 5 min of removing the sample from the conditioning atmosphere.	22°C, 53% 5min	P
4.1.2	Mechanical and flammability requirements	Mechanical: tensile strength: >=60N and <=100N Puncture resistance: >=10N and <=50N Tear strength: >=20N and <=40N	P
	The materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.	Flammability: Damage length <= 105mm; continued time <=5s; flame retardant time <=5s	P
4.1.3	Chemical requirements		N/A
	If protection against chemicals is claimed, the materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.		N/A
4.1.4	Performance requirements against penetration by infective agents		P
4.1.4.1	Resistance to penetration by contaminated liquids under hydrostatic pressure		P
	Table 1 — Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (ISO/FDIS 16604)	2: 103 kPa Class 2: ≥ 1.5 kPa	P

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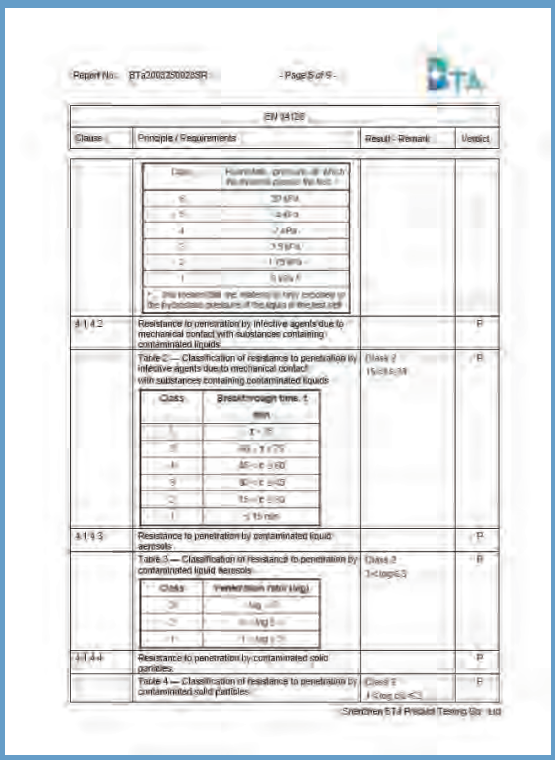

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EN 14126			
Clause	Principle / Requirements	Result - Remark	Verdict
	Class / Hydrostatic pressure at which the first three drops appear (kPa)		
	6 / 20 kPa		
	5 / ≥ 14 kPa		
	4 / ≥ 7 kPa		
	3 / ≥ 3,5 kPa		
	2 / ≥ 1,75 kPa		
	1 / ≥ 0,69 kPa		
	* the material can be relatively easily crossed by the hydrostatic pressure of the liquid in the test cell		
4.1.4.2	Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids		P
	Table 2 — Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids	Class 2 15<t≤30	P
	Class / Breakthrough time, t, min		
	6 / t > 30		
	5 / 480 > t ≥ 30		
	4 / 240 > t ≥ 60		
	3 / 120 > t ≥ 60		
	2 / 30 > t ≥ 60		
	1 / t ≤ 15 min		
4.1.4.3	Resistance to penetration by contaminated liquid aerosols		P
	Table 3 — Classification of resistance to penetration by contaminated liquid aerosols	Class 2 1<log≤3	P
	Class / Penetration ratio (-log)		
	6 / -log > 6		
	5 / 6 ≥ -log > 3		
	4 / 3 ≥ -log > 1		
	3 / 1 ≥ -log > 0		
4.1.4.4	Resistance to penetration by contaminated solid particles		P
	Table 4 — Classification of resistance to penetration by contaminated solid particles	Class 1 1 ≤ log 0S < 3	P

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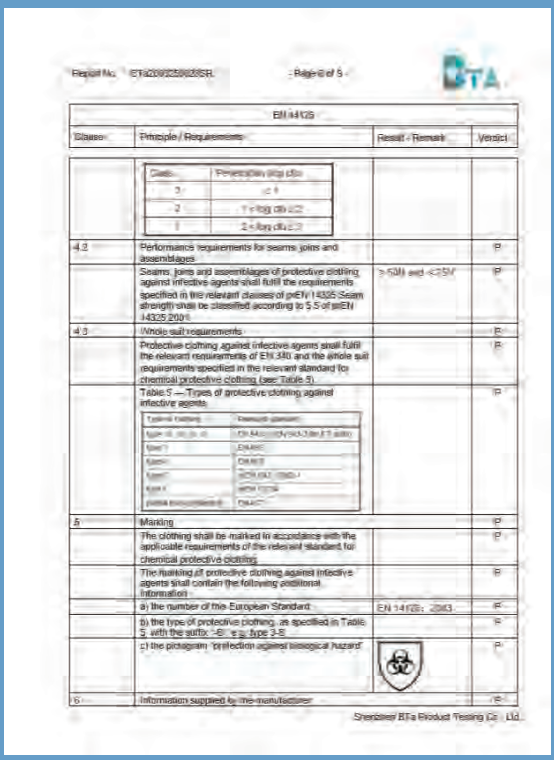

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EN 14126			
Clause	Principle / Requirements	Result - Remark	Verdict
	Class / Penetration (-log cfu)		
	3 / ≥ 6		
	2 / 4 ≤ -log cfu < 6		
	1 / 2 ≤ -log cfu < 4		
4.2	Performance requirements for seams, joins and assemblages		P
	Seams, joins and assemblages of protective clothing against infective agents shall fulfil the requirements specified in the relevant clauses of prEN 14325 Seam strength shall be classified according to 5.5 of prEN 14325:2003	> 50N and <125N	P
4.3	Whole suit requirements		P
	Protective clothing against infective agents shall fulfil the relevant requirements of EN 340 and the whole suit requirements specified in the relevant standard for chemical protective clothing (see Table 5)		P
	Table 5 — Types of protective clothing against infective agents		P
	Typical marking / Relevant standard		
	Type 1 / EN 943-1		
	Type 2 / EN 943-2		
	Type 3 / EN 14605 Type 3		
	Type 4 / EN 14605 Type 4		
	Type 5 / EN 14605		
	Type 6 / EN 13034		
5	Marking		P
	The clothing shall be marked in accordance with the applicable requirements of the relevant standard for chemical protective clothing		P
	The marking of protective clothing against infective agents shall contain the following additional information		P
	a) the number of this European Standard	EN 14126: 2003	P
	b) the type of protective clothing, as specified in Table 5, with the suffix "-B", e.g. type 3-B		P
	c) the pictogram "protection against biological hazard"		P
6	Information supplied by the manufacturer		P

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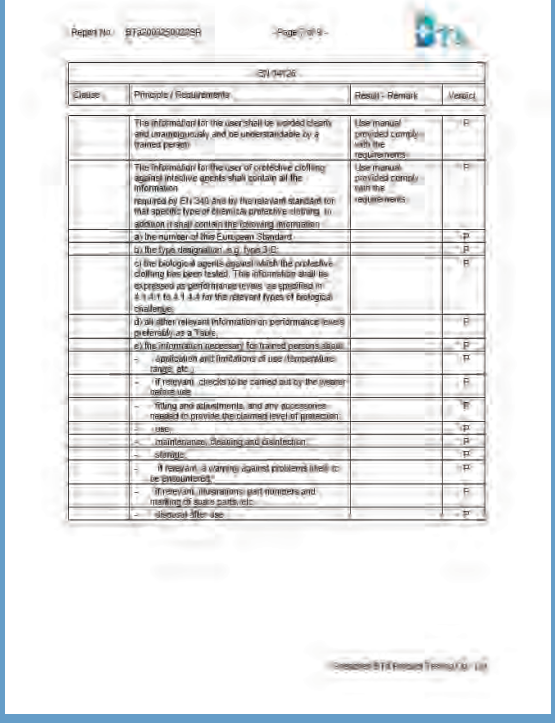

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EN 14126			
Clause	Principle / Requirements	Result - Remark	Verdict
	The information for the user shall be worded clearly and unambiguously, and be understandable by a trained person	Use manual provided comply with the requirements	P
	The information for the user of protective clothing against infective agents shall contain all the information required by EN 340 and by the relevant standard for that specific type of chemical protective clothing. In addition it shall contain the following information	Use manual provided comply with the requirements	P
	a) the number of this European Standard		P
	b) the type designation, e.g. type 3-B;		P
	c) the biological agents against which the protective clothing has been tested. This information shall be expressed as performance levels, as specified in 4.1.4.1 to 4.1.4.4 for the relevant types of biological challenge;		P
	d) all other relevant information on performance levels preferably as a Table;		P
	e) the information necessary for trained persons about:		P
	– application and limitations of use (temperature range, etc.);		P
	– if relevant, checks to be carried out by the wearer before use;		P
	– fitting and adjustments, and any accessories needed to provide the claimed level of protection;		P
	– use;		P
	– maintenance, cleaning and disinfection;		P
	– storage;		P
	– if relevant, a warning against problems which can be encountered;		P
	– if relevant, illustrations, part numbers and marking of spare parts etc.		P
	– disposal after use.		P

Shenzhen BTa Product Testing Co., Ltd.

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Attachment 1:

Photo-documentation

Shenzhen BTa Product Testing Co., Ltd.

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Xinxiang City, Henan Province

Attachment 1:

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

Shenzhen BTa Product Testing Co., Ltd..

Yu'an (Henan) Holding Co., Ltd
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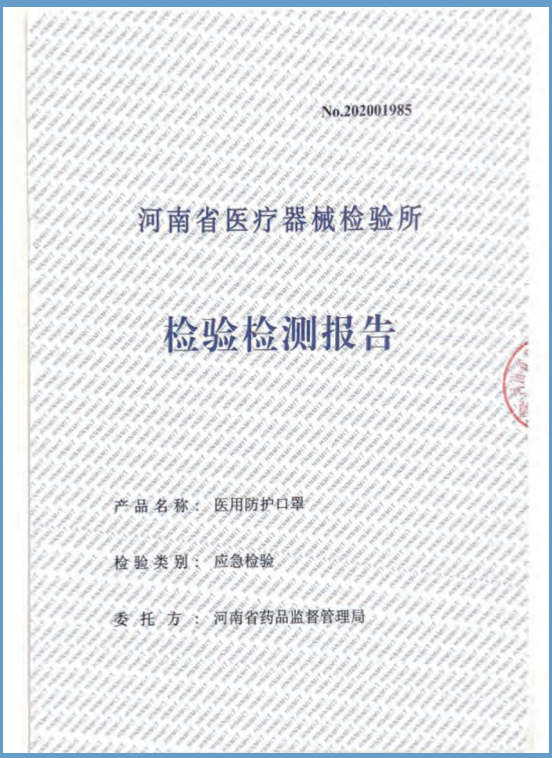
Xinxiang City, Henan Province

一次性医用防护服纸塑袋

一次性医用防护服纸箱

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province



No.202001985

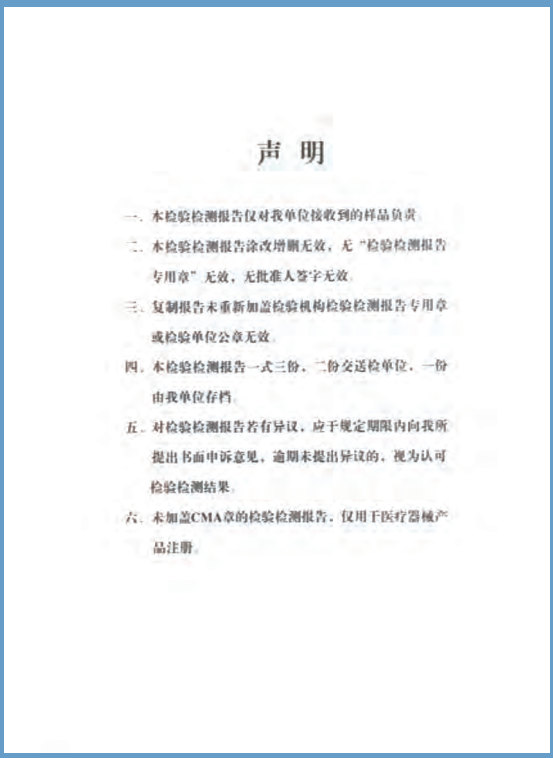
河南省医疗器械检验所

检验检测报告

产品名称：医用防护口罩

检验类别：应急检验

委托方：河南省药品监督管理局



声 明

一、本检验检测报告仅对我单位接收到的样品负责。

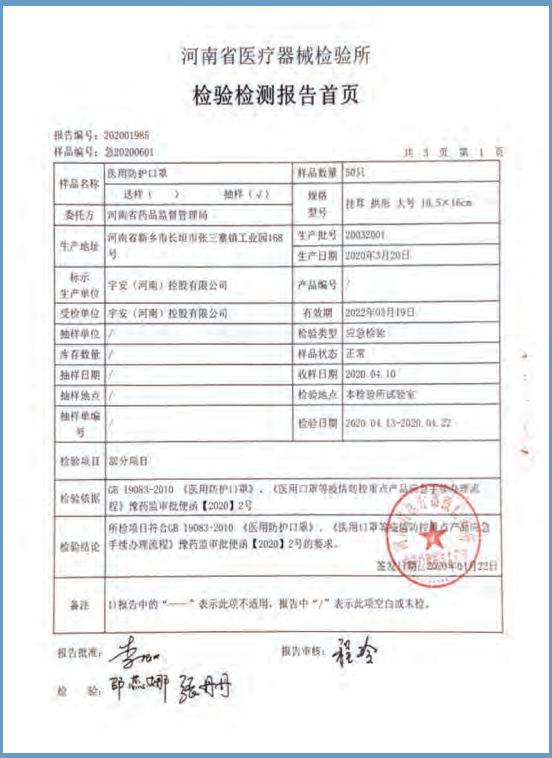
二、本检验检测报告涂改增删无效，无"检验检测报告专用章"无效，无批准人签字无效。

三、复制报告未重新加盖检验机构检验检测报告专用章或检验单位公章无效。

四、本检验检测报告一式三份，二份交送检单位，一份由我单位存档。

五、对检验检测报告若有异议，应于规定期限内向我所提出书面申诉意见，逾期未提出异议的，视为认可检验检测结果。

六、未加盖CMA章的检验检测报告，仅用于医疗器械产品注册。



河南省医疗器械检验所

检验检测报告首页

报告编号：202001985
样品编号：急20200601

共 3 页 第 1 页

样品名称	医用防护口罩	样品数量	50只
	选样（ ） 抽样（√）	规格型号	挂耳 拱形 大号 10.5×16cm
委托方	河南省药品监督管理局		
生产地址	河南省新乡市长垣市张三寨镇工业园168号	生产批号	20032001
		生产日期	2020年3月20日
标示生产单位	宇安（河南）控股有限公司	产品编号	/
受检单位	宇安（河南）控股有限公司	有效期	2022年03月19日
抽样单位	/	检验类型	应急检验
库存数量	/	样品状态	正常
抽样日期	/	收样日期	2020.04.10
抽样地点	/	检验地点	本检验所试验室
抽样单编号	/	检验日期	2020.04.13~2020.04.22
检验项目	部分项目		
检验依据	GB 19083-2010 《医用防护口罩》、《医用口罩等疫情防控重点产品应急处理流程》豫药监审批便函【2020】2号		
检验结论	所检项目符合GB 19083-2010 《医用防护口罩》、《医用口罩等疫情防控重点产品应急手续办理流程》豫药监审批便函【2020】2号的要求。 签发日期：2020年04月22日		
备注	1)报告中的"——"表示此项不适用，报告中"/"表示此项空白或未检。		

报告批准：　　报告审核：

检　验：

河南省医疗器械检验所

检验检测报告

样品编号：急20200601

共 3 页 第 2 页

医用防护口罩

检验项目	标准条款	标准要求	检验结果	单项结论
鼻夹	4.2.1	口罩上应配有鼻夹	符合要求	合格
	4.2.2	鼻夹应具有可调节性	符合要求	合格
口罩带	4.3.1	口罩带应调节方便	符合要求	合格
	4.3.2	应有足够强度固定口罩位置，每根口罩带与口罩体连接点的断裂强力应不小于10N。	符合要求	合格
过滤效率	4.4	在气体流量为85L/min情况下，口罩对非油性颗粒过滤效率应符合表1的要求（≥95%）	温度预处理前最小：99.38%，温度预处理后最小：99.41%	合格
合成血液穿透	4.6	将2mL合成血液以10.7kPa（80 mmHg）压力喷向口罩，口罩内侧不应出现渗透。	符合要求	合格
微生物指标	4.8.1	口罩应符合GB15979-2002中微生物指标的要求，见表2（细菌菌落总数≤200CFU/g，大肠菌群不得检出，绿脓杆菌不得检出，金黄色葡萄球菌不得检出，溶血性链球菌不得检出，真菌菌落总数≤100CFU/g）	细菌菌落总数(20cfu/g，真菌菌落总数(20cfu/g，大肠菌群、金黄色葡萄球菌、绿脓杆菌、溶血性链球菌均未检出。	合格
密合性	4.12	口罩设计应提供良好的密合性，口罩总适合因数应不低于100	符合要求	合格

备注：
以下空白

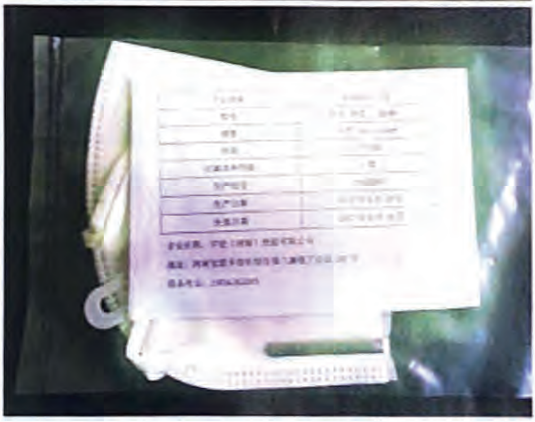
Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

河南省医疗器械检验所

检验检测报告照片页

样品编号：豫20200601　　共 3 页 第 1 页

照片说明



样品描述

型号规格或其他说明

产品标示型号规格：挂耳 拱形 大号 10.5×16cm

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

民用防护口罩纸塑袋

民用防护口罩纸箱

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

民用防护口罩英文纸盒包装

民用防护口罩英文纸塑袋

Yu'an (Henan) Holding Co., Ltd
ADD.No. 168, industrial park, zhangsanzhai Town, Changyuan City,
Xinxiang City, Henan Province

民用防护口罩纸盒包装

民用防护口罩纸塑袋

民用防护口罩纸箱

Yu'an (Henan) Holding Co., Ltd
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Xinxiang City, Henan Province

YU'AN (HENAN) HOLDING CO., LTD

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Xinxiang City, Henan Province