湖南豌豆医疗用品有限公司

医用外科口罩资质文件

Hunan Wondo Medical Supplies Co . , Ltd

Medical Surgical Face Mask

Qualification Documents

序号 Serial number	文件明细 File details		英文 English
1	企业信息	企业简介	Company Profile
2		营业执照	Business license
3		生产许可证	Manufacture Lciense of Medical Device
4		高新技术企业证书	/
5		对外贸易经营者备案	Record of foreign trade operators
6		账户信息	Bank information
7	产品信息	中国医疗器械注册证	Certificate of CFDA Regisitration
8		中国检测报告	Inspection Report
9		出口销售证明	Export sales certificate
10		CE 认证流程说明	CE procedure
11		CE 符合性声明	DoC
12		TÜV 检测报告	TÜV Inspection Report
13		CE 备案凭证	CE Filing Certificate
14		医用外科口罩包装信息	Medical Surgical Face Mask Packaging information

企业简介 Company Profile

企业介绍

湖南豌豆医疗用品有限公司成立于2016年，注册资金3000万元，总部位于国家级长沙经济技术开发区铭城绿谷产业园，是一家覆盖医疗耗材和家用医疗产品两个领域的研发、生产、销售和服务为一体的**科创型制造企业**。本着“让创新科技温暖生命”的产品理念，致力于为客户提供最专业的医疗健康产品系统性解决方案。

豌豆医疗
（多元化综合性医疗集团）

1. 医疗科技研发
2. 医疗器械生产
3. 医疗贸易服务
4. 临床医疗学术服务
5. 医疗项目投资管理

wondo 豌豆医疗 行不止 · 创未来

企业规模

- 标准化生产车间约**2200**平方米
- 十万级净化车间约**1300**平方米
- 研发中心及万级净化生物实验室约**500**平方米
- 医疗耗材专业化仓库**1100**平方米
- 配备先进的生产设备、百级工作台及精密的科研仪器
- 依照ISO9001和ISO13485建立**标准化质量管理体系**

优质企业

省科技厅入库中小型科技企业

湖南省2019年第一批通过国家级高新技术企业

湘雅医院创新科技成果转化签约合作方

湖南省食品药品监督管理局重点项目单位

长沙经济技术开发区重点培育企业

湖南省医疗器械行业协会副会长单位

湖南师范医学院、食品药品职业学院等高校合作单位

长沙市级疫情防控期间重点联系企业

营业执照

Business license

统一社会信用代码

91430100MA4L72L19J

营业执照

名　　称　湖南豌豆医疗用品有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　谭周辉

经 营 范 围　一类医疗器械、二类医疗器械、三类医疗器械的生产；医疗器械技术推广服务；一类医疗器械、二类医疗器械的销售；三类医疗器械批发；三类医疗器械零售；一类医疗器械、二类医疗器械、三类医疗器械的研发；自营和代理各类商品及技术的进出口，但国家限定公司经营或禁止进出口的商品和技术除外；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）。（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　叁仟万元整

成 立 日 期　2016年10月27日

营 业 期 限　2016年10月27日至 2066年10月26日

住　　所　长沙经济技术开发区人民东路二段169号先进储能节能创意示范产业园12栋502

登记机关

2020 年 4 月 2 日

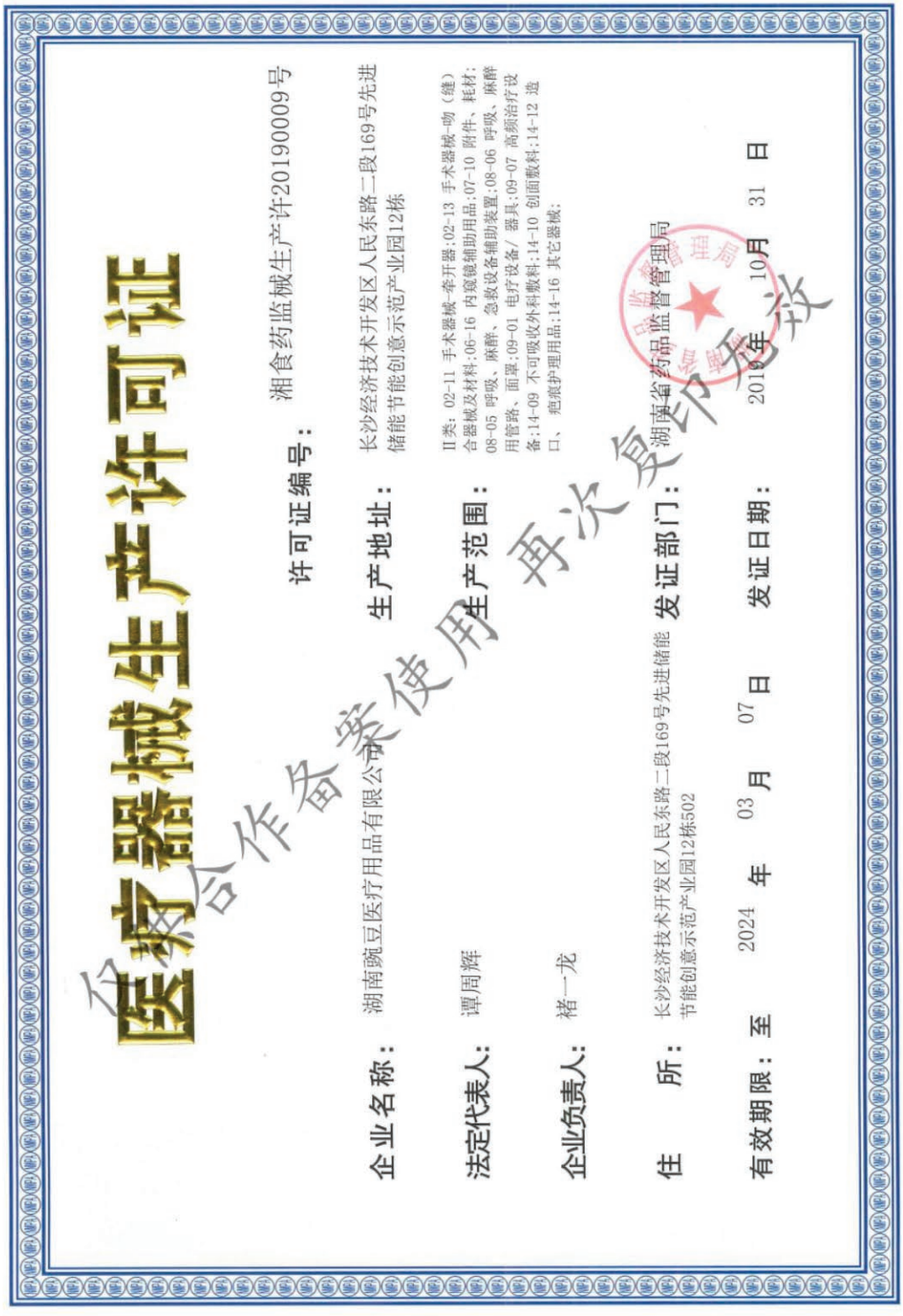
扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

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

生产许可证

Manufacure Lcense of Medical Device



高新技术企业

证书

证书编号：GR201943000080

企业名称：湖南豌豆医疗用品有限公司

有 效 期：三年

发证时间：2019 年 9 月 5 日

批准机关：

对外贸易经营者备案登记表

Record of foreign trade operators

对外贸易经营者备案登记表

统一社会信用代码：91430100MA4L72L19J

备案登记表编号：04748799　　进出口企业代码：

经营者中文名称	湖南豌豆医疗用品有限公司		
经营者英文名称	Hunan WonDo Medical Supplies CO., LTD.		
组织机构代码	---------	经营者类型（由备案登记机关填写）	有限责任公司
住　所	长沙经济技术开发区人民东路二段169号先进储能节能创意师范产业园12栋502		
经营场所（中文）	长沙经济技术开发区人民东路二段169号先进储能节能创意师范产业园12栋502		
经营场所（英文）	Building 12th, Advanced Energy Storage and Energy Saving of Creative Industrial Park, No. 169, 2nd, Area East Renmin Road, Changsha Economic and Technological Development Zone, Hunan, Province,China.		
联系电话	18673174032	联系传真	073186880007
邮政编码	410000	电子邮箱	524801237@QQ.COM
工商登记注册日期	2019-1-9	工商登记注册号	----------

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	谭周辉	有效证件号	430103198006154061
注册资金	叁仟万元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产			（折美元）

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关

签　章

2020 年 03 月 31 日

中国医疗器械注册证

Certificate of CFDA Regisitration

中华人民共和国医疗器械注册证

注册证编号：湘械注准20202140333

注册人名称	湖南豌豆医疗用品有限公司
注册人住所	长沙经济技术开发区人民东路二段169号先进储能节能创意示范产业园12栋502
生产地址	长沙经济技术开发区人民东路二段169号先进储能节能创意示范产业园12栋
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（非无菌型）
型号、规格	型号：平面形（耳挂式、绑带式），尺寸规格为17cm×9cm。
结构及组成	本产品由口罩体、鼻夹、口罩带组成。口罩体分为内、中、外三层组成，内层、外层为为无纺布，中层为熔喷无纺布，口罩带由松紧带制成，鼻夹由可弯折的聚丙烯材料制成。产品为非无菌供应。
适用范围	适用于医务人员或相关人员的基本防护，以及在有创操作过程中阻止体液和喷溅物传播的防护。
附 件	产品技术要求
其他内容	
备 注	1. 该产品为应急审批注册，有效期为八个月；2. 该产品在延续/变更注册时应按医疗器械注册管理要求完善相关资料。

审批部门：湖南省药品监督管理局　　批准日期：2020年03月07日

有效期至：2020年11月06日

湖南省药品监督管理局 医疗器械注册专用章

中国检测报告

Inspection Report

检 验 报 告

报告编号：YQ202030272

委托单位 湖南豌豆医疗用品有限公司

样品名称 医用外科口罩

型 号 C

检验类别 注册检验

湖南省医疗器械检验检测所

湖南省医疗器械检验检测所

检 验 报 告 首 页

报告编号： YQ202030272

样品名称	医用外科口罩	样品编号	YQ202030272
型号规格	C	商 标	佰合
委托单位	湖南豌豆医疗用品有限公司	检验类别	注册检验
委托单位地址	长沙经济技术开发区人民东路二段169号先进储能节能创意示范产业园12栋	产品编号/批号	2002001
生产单位	湖南豌豆医疗用品有限公司	抽样单/协议编号	QX202000492
受检单位	湖南豌豆医疗用品有限公司	生产日期	2020.02.16
抽样单位	/	样品数量	20 个
抽样地点	/	抽样基数	/
抽样日期	/	检验地点	长沙市八一路60号
收样日期	2020-03-03	检验日期	2020-03-04 ～ 2020-03-07
检验项目	单项检验		
检验依据	湖南豌豆医疗用品有限公司医用外科口罩产品技术要求		
检验结论	被检样品受检项目符合湖南豌豆医疗用品有限公司医用外科口罩产品技术要求。 （检验报告专用章或检验单位公章） 签发日期 2020-03-09		
备注	1）报告中的“——”表示此项不适用，报告中“/”表示此项空白。 2）应急注册检验，本品为非无菌产品。 3）细菌过滤效率（BFE）系委托湖南省药品检验研究院（湖南药用辅料检验检测中心）检验（证书编号：15180014017）		

批准： 黄西平 审 核： 刘国国 检 验： 彭婉琴

职务： 副所长

湖南省医疗器械检验检测所

检 验 报 告

报告编号:YQ202030272

序号	检验项目	标准条款	标准要求	检验结果	单项结论	备注
1	细菌过滤效率（BFE）	2.6.1	口罩的细菌过滤效率应不小于95%	98.9%	符合	/

以下空白

湖南省医疗器械检验检测所

检 验 报 告

报告编号:YQ202030178

序号	检验项目	标准条款	标准要求	检验结果	单项结论	备注
1	合成血液穿透	2.5	2ml合成血液以16.0kPa（120mmHg）压力喷向口罩外侧面后，口罩内侧面不应出现渗透（3/0）	符合要求（3/0）	符合	/
2	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%（3/0）	43%～44%（3/0）	符合	/

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出口销售证明

Export sales certificate

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：湘药监械出 20200064 号
Certificate NO.: HNMPA 20200064

产品名称：医用外科口罩
Product(s): Medical Surgical Face Mask

规格型号：平面形（耳挂式、绑带式），尺寸规格为 17cm × 9cm，允差 5%
Model: Flat form（ear loop and lexpert-up）Size, 17cm × 9cm, deviation 5%

产品注册或备案凭证号：湘械注准 20202140333
Registration certificate(s): HNMPA Certified 20202140333

生产企业：湖南豌豆医疗用品有限公司
Manufacturer: Hunan Wondo Medical Supplies Co ., Ltd.

生产企业住所：长沙经济技术开发区人民东路二段 169 号先进储能节能创意示范产业园 12 栋 502
Address of manufacturer: Building 12th, Advanced Energy Storage and Energy Saving of Creative Industrial Park, No. 169, 2nd, Area East Renmin Road, Changsha Economic and Technological Development Zone, Hunan, Province, China.

生产许可或备案凭证号：湘食药监械生产许 20190009 号
Manufacturing License(s): Hunan CFDA Production Permit No. 20190009 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2022 年 4 月 12 日
This certification valid until: Apr. 12, 2022

湖南省药品监督管理局
HUNAN MEDICAL PRODUCTS ADMINISTRATION
2020 年 4 月 13 日
Apr. 13, 2020

CE 认证流程说明

CE procedure

豌豆医疗 CE 认证流程

1、自我符合性声明（包括欧代信息、产品类别、引用标准、符合欧盟法规 MDR 等信息）；

2、由欧盟委员会授权的（中国仅 3 家）、具有 MDR 审核资质的公告机构南德认证检测（TÜV SÜD）出具产品的相关检测报告；

3、欧代完成审定并递交德国主管当局（药监局）备案，德国药主管当局出具官方签字版的备案凭证，该凭证代表我公司产品符合欧盟标准并具有 CE 出口资质。

湖南豌豆医疗用品有限公司

2020 年 3 月 25 日

CE 符合性声明

Declaration of Conformity

European Commission

Declaration of Conformity

Manufacturer: Hunan Wondo Medical Supplies Co., Ltd.
Address: Building 12th, Advanced Energy Storage and Energy Saving of Creative Industrial Park, No. 169, 2nd, Area East Renmin Road, Changsha Economic and Technological Development Zone, Hunan, Province, China

EU Authorised Representative:
Osmunda Medical Technology Service GmbH
Address: Von Oppen-Weg 15, 14476 Potsdam, Germany
DIMDI code: DE/0000047267

Device: Medical surgical face mask
Model: Flat form (ear loop and lexpert-up); Folded form
Classification (MDR, Annex VIII): Class I
Conformity assessment route: ANNEX II+ANNEX III

We herewith declare that the above mentioned product meet the provisions of the following regulation (EU) MDR 2017/745. All supporting documentations are retained under the premises of the manufacturer.

CE

General applicable directives:
Medical Device Directive: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

Standard Applied:

EN ISO 13485:2016	EN ISO 14971:2012	EN 14683:2019 +AC: 2019	BS EN ISO 15223-1:2016
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	ISO 10993-10:2010	EN 1041:2008

Place, Date of Issue:
Changsha, 30th March 2020

Signature:
Manager representative

TÜV 检测报告

TÜV Inspection Report

Test Report No.: 721653785-11
Report Date: 23 April 2020

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Hunan Wondo Medical Supplies Co., Ltd**
CLIENT ADDRESS	Building 12th, Advanced Energy Storage and Energy Saving of Creative Industrial Park, No. 169, 2nd, Area East Renmin Road, Changsha Economic and Technological Development Zone, Hunan, Province,China.
TEST PERIOD	08-Apr-2020~16-Apr-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

Leo Liu

(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax: +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Test Report No.: 721653785-11
Report Date: 23 April 2020

TEST REPORT

Sample Description	:	Medical Surgical Face Mask
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	20200324
Specification	:	Flat form ear loop
Size	:	17cm*9cm
Type of Mask	:	Type IIR
Brand Name	:	/

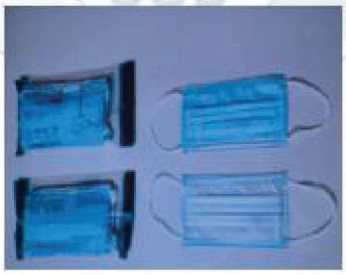
Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples



Test Report No.: 721653785-11
Report Date: 23 April 2020

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.5% Specimen 2#: 99.4% Specimen 3#: 99.4% Specimen 4#: 99.5% Specimen 5#: 99.5%
2	Differential Pressure Test	26.5 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 5 CFU/g Specimen 2#: 27 CFU/g Specimen 3#: 13 CFU/g Specimen 4#: 10 CFU/g Specimen 5#: 8 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. **Purpose**

   For evaluating the bacterial filtration efficiency (BFE) of mask.

2. **Sample description was given by client**

   Sample description : Medical Surgical Face Mask
   Specification : Flat form ear loop
   Lot Number : 20200324
   Sample Receiving Date : 2020-04-08

3. **Test Method**

   EN 14683:2019+AC:2019(E) Annex B

4. **Apparatus and materials**

   4.1 *Staphylococcus aureus* ATCC 6538.
   4.2 Peptone water.
   4.3 Tryptic Soy Broth(TSB).
   4.4 Tryptic Soy Agar(TSA).
   4.5 Bacterial filtration efficiency test apparatus.
   4.6 Six-stage viable particle Anderson sampler.
   4.7 Flow meters.

5. **Test specimen**

   5.1 As requested by client, take a total of 5 test specimens.
   5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T)/C\times100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	33	55	0	0	0	0	0	0
2	120	246	0	2	2	2	2	2
3	112	294	0	1	0	1	1	1
4	119	298	0	0	0	0	0	0
5	1341	1219	0	4	4	3	4	4
6	347	450	0	4	7	7	5	4
Total (*T*), CFU	2072	2562	<1	11	13	13	12	11
Average (C), CFU	$2.3 \times 10^3 = (P_A+P_B) / 2$							
BFE ,%				99.5	99.4	99.4	99.5	99.5
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

Test Report No.: 721653785-11
Report Date: 23 April 2020

Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description	:	Medical Surgical Face Mask
Specification	:	Flat form ear loop
Lot Number	:	20200324
Sample Receiving Date	:	2020-04-08

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm², test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm²)	Average (Pa/cm²)	Requirements	Judgement
1#	27.1	26.5	< 60	Pass
2#	26.6			
3#	24.3			
4#	25.0			
5#	29.5			

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Test Report No.: 721653785-11
Report Date: 23 April 2020

Synthetic Blood Penetration Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	Medical Surgical Face Mask
Specification	:	Flat form ear loop
Lot Number	:	20200324
Sample Receiving Date	:	2020-04-08

3.Test Method

ISO 22609:2004

4.Apparatus and materials

4.1 Synthetic blood.
4.2 Tensiometer.
4.3 Synthetic blood penetration test apparatus;
4.4 Targeting plate.
4.5 Air pressure source.
4.6 Ruler.
4.7 Balance.
4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 13 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
6.2 Determine the density of the synthetic blood.
6.3 Fill the reservoir with new synthetic blood.
6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
6.5 Set the reservoir pressure to the approximate pressure.
6.6 Place the targeting plate approximately 1 cm away from the mask.
6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).
6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting

hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
(p is the density of the test fluid.) $t = 0.5 + (2\times p$ - g at 0.5 s) / (g at 1.5 s - g at 0.5 s).

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

Chemical/Microbiology Laboratory:
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Report Date: 23 April 2020

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass

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Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description	:	Medical Surgical Face Mask
Specification	:	Flat form ear loop
Lot Number	:	20200324
Sample Receiving Date	:	2020-04-08

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

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Test Report No.: 721653785-11
Report Date: 23 April 2020

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	4	1	5	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤30 CFU/g tested.	Pass
2#	15	12	27		
3#	7	6	13		
4#	8	2	10		
5#	7	1	8		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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CE 备案凭证

CE Filing Certificate

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00301438

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority	
Code **DE/CA76**	
Bezeichnung / Name **Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit, Abteilung Gesundheit, Dezernat G4**	
Staat / State **Deutschland**	Land / Federal state **Brandenburg**
Ort / City **Zossen**	Postleitzahl / Postal code **15806**
Straße, Haus-Nr. / Street, house no. **Wünsdorfer Platz 3**	
Telefon / Phone **+49-331-8683852**	Telefax / Fax **+49-331-8683865**
E-Mail / E-mail **medizinprodukte@lavg.brandenburg.de**	

Anzeige / Notification	
Registrierdatum bei der zuständigen Behörde Registration date at competent authority	Registriernummer / Registration number
Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal	
Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn	
Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG	

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00301438

Anzeigender / Reporting organisation (person)			
	Code **DE/0000047267**		
	Bezeichnung / Name **Osmunda Medical Technology Service GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Brandenburg**
	Ort / City **Potsdam**		Postleitzahl / Postal code **14476**
	Straße, Haus-Nr. / Street, house no. **Von Oppen-Weg, 15**		
	Telefon / Phone **030 50590627**		Telefax / Fax
	E-Mail / E-mail **eu@osmundacn.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Hunan Wondo Medical Supplies Co., Ltd**		
	Staat / State **CN**		
	Ort / City **Changsha, Hunan**		Postleitzahl / Postal code **410000**
	Straße, Haus-Nr. / Street, house no. **Building 12th, Advanced Energy Storage and Energy Saving of Creative Industrial Park, No. 169, 2nd, Area East Renmin Road, Changsha Economic and Techn**		
	Telefon / Phone [redacted]		Telefax / Fax
	E-Mail / E-mail		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG			
	Bezeichnung / Name **Min Yang**		
	Staat / State **Deutschland**		Land / Federal state **Berlin**
	Ort / City **Berlin**		Postleitzahl / Postal code **10787**
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Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00301438

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change		

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00301438

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class ☒ I ☐ I - steril / sterile ☐ I - mit Messfunktion / with measuring function ☐ I - steril und mit Messfunktion / sterile and with measuring function ☐ IIa ☐ IIb ☐ III ☐ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 ☐ Aktives implantierbares Medizinprodukt / Active implantable medical device ☐ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012
	App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **Medical surgical face mask**
	Produktbezeichnung / Name of device
	Nomenklaturcode / Nomenclature code **12-458**
	Nomenklaturbezeichnung / Nomenclature term **Maske, Chirurgie**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description **The medical surgical face mask is suitable for medical workers basic protection and related workers under environment with the risk of body fluid and spatter.**

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00301438

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	☐ Semikritische Medizinprodukte / Semicritical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B
	☐ Kritische Medizinprodukte / Critical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B ☐ Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures ☐ Dampfsterilisation / Steam sterilisation ☐ Gassterilisation / Gas sterilisation ☐ Strahlensterilisation / Radiation sterilisation ☐ andere / others Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Berlin**

Datum
Date **2020-04-05**

Name **Min Yang**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible		Telefon / Phone

包装信息

Packaging information

初包装：18cm*29cm

50 片/包

中盒：8cm*11cm*20cm

1 包/盒

外箱：40 盒/箱

34cm*42cm*57cm

QTY/BOX：50Pcs

QTY of BOXES/CARTON:40 boxes

QTY/CARTON:2000Pcs

G.W: 8.7KG

N.W:6.4KG

MEAS: 57CM×42CM×34CM