



Single-use Face Mask(Non-sterile)

- **For Surgical**
 - **For Medical**
 - **Non Medical**
- EN14683 Type IIR, Type II, Type I
- GBT 32610-2016

3-ply, 50pcs x 40boxes.

SGS, CIGB Registration Certification, CE Declaration of Conformity.

White list of the Ministry of Commerce of China. (No.783)

Accept Deposit and Production Schedule
Daily production capacity: 30,000,000 PCS

- ✓ In Stock
- ✓ Accept Order of 100,000 PCS or 1,000,000 PCS
- ✓ Order of 100,000,000+ PCS will be preferred.

Carton size: 52*38*34cm, 40 box/carton, G.W.: 7.4kg, N.W.: 5.35kg

CIBG

REGISTRATION CERTIFICATION



CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 16114 2500 DC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 21 april 2020
Betreft: aanmelding medisch hulpmiddel Klasse I

Geachte heer Wei,

Graag bevestig ik hierbij de ontvangst op 4 april 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Zhejiang The Purples Protective Products Co.,Ltd met Europees gemachtigde Lotus NL B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

Single-use face mask(non-sterile)
(geen merknaam) (NL-CA002-2020-50323)

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voorschrijvend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling - verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse taaleisen, die eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiestelsel.

Farmatec

Bezoekadres:
Hofflaan
Rijstraat 50
2515 XP Den Haag
T 070 340 6161

<http://www.farmatec.nl>

Inlichtingen bij:

T.I. van Lanzeveld - Daas
medische_hulpmiddelen@
mivvas.nl

Ons kenmerk:
CIBG-20201229

Bijlagen

-

Uw aanvraag
4 april 2020

*Correspondentie uitsluitend
relatie aan het contactadres met
vermelding van de datum en het
kenmerk van deze brief.*

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde
Dir. M.J. van de Velde

SGS EN14683



中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report SL52025244048101TX Date: April 21, 2020 Page 1 of 3
ZHEJIANG THE PURPLE'S PROTECTIVE PRODUCTS CO., LTD
1/F, NORTH ZONE, BUILDING B, NO.66, QUNYING ROAD, HOUZHAI, YIWU, ZHEJIANG PROVINCE

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)Face mask
Style No. : TP-001
Composition : (A)NONWOVEN MELT-BLOWN FABRIC
Sample Color : (A)blue
Manufacturer : ZHEJIANG THE PURPLE'S PROTECTIVE PRODUCTS CO., LTD

Proposed Care Instruction : -

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Apr 02, 2020
Testing Period : Apr 02, 2020 - Apr 21, 2020

Test Result(s) : For further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo

Sara Guo (Account Executive)



Test Report SL52025244048101TX Date: April 21, 2020 Page 2 of 3

Test Result

Medical Face Masks-Requirements and Test Methods
(EN 14683:2019)

Clause 5.2.2 Bacterial filtration efficiency (BFE)*

(BFE), %	1#	2#	3#	4#	5#
	99.9	99.2	99.8	99.6	99.7

Remark: Performance Requirement: Type I > 95%, Type II > 98%, Type IIR > 98%
*: The test was carried out by external laboratory assessed as competent
@: These test methods are not in CNAS accredited scope

Clause 5.2.3 Breathability
(EN 14683:2019 Annex C, Flow rate 8 l/min)

Differential pressure ΔP (Pa/cm ²)	1#	2#	3#	4#	5#
	59.9	58.7	58.1	58.6	57.3

Recommended Level: Type IIR
Remark: Performance Requirement: Type I < 40 Pa/cm², Type II < 40 Pa/cm², Type IIR < 60 Pa/cm²

Clause 5.2.4 Splash Resistance
(ISO 22659:2004, Pressure 16.0 kPa)

Penetration on inside surface

1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Fail	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Fail	Pass	Pass	Pass	Pass	Pass

Number of Pass: 30
Overall result: Acceptable

Remark:
1) Performance Requirement Type I: NA, Type II: NA, Type IIR > 16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results



Test Report SL52025244048101TX Date: April 21, 2020 Page 3 of 3

Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019 Annex D)

CFU/g	1#	2#	3#	4#	5#
	9	8	8	6	6

Remark: Performance Requirement: Type I < 30 CFU/g, Type II < 30 CFU/g, Type IIR < 30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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中国 - 上海 - 保工区宝山路869号4楼 邮编: 200233 电话: (86-21)642936 传真: (86-21)649873

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中国 - 上海 - 保工区宝山路869号4楼 邮编: 200233 电话: (86-21)642936 传真: (86-21)649873

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DECLARATION OF CONFORMITY



DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

Manufacturer:

Name: Zhejiang The Purples Protective Products Co.,Ltd
 Address: 1/F, North Zone, Building B, No.66, Qunying Road, Houzhai, Yiwu, Jinhua, Zhejiang, China
 Telephone: 86-579-85091111
 E-mail: ztp@ztp.com.cn

Whose Authorized Representative:

Name: Lotus NL B.V.
 Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
 E-mail: general@lotus.nl

We, the manufacturer, herewith declare that the products

Product Name	Medical Device	Device Class	Model	UMDN S Code	Basic UDI-DI
Disposable Medical Face Mask (Non sterile)	Masks	I, Rule1 (Annex VIII of MDR)	TP-100	12447	

meet the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

Applicable Standards:

ISO 13485:2016 ISO 14971:2019 ISO 10993-1: 2018
 ENISO 10993-5: 2009 ENISO 10993-10: 2013 EN 14683:2019+AC
 EN 1041:2008 EN 29073-1:1992 EN ISO 9073-15-2008
 EN 15223-1:2016

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Zeng Yuqing

Signature:

Position held in the company: General Manager

Date:

Place: Zhejiang, China

Zhejiang The Purples Protective Products Co.,Ltd

Seal/Stamp:



ENTERPRISE
INFORMATION


营业执照
(副本)

统一社会信用代码
91330782MA2HR99B5W (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	浙江紫家防护用品有限公司	注册资本	壹亿元整
类型	有限责任公司（自然人投资或控股的法人独资）	成立日期	2020年03月27日
法定代表人	谢江	营业期限	2020年03月27日至长期
经营范围	一般项目：医护人员防护用品生产（I类医疗器械）；医护人员防护用品批发；医护人员防护用品零售；特种劳动防护用品生产；特种劳动防护用品销售；产业用纺织制成品制造；产业用纺织制成品销售；塑料制品制造；塑料制品销售；纸制品制造；纸制品销售；服装制造；服装服饰批发；服装服饰零售；第一类医疗器械生产；第一类医疗器械销售；第二类医疗器械销售；日用杂品制造；日用杂品销售；医用口罩零售；医用口罩（非医用）生产；医用口罩（非医用）销售；医用口罩批发；卫生用品和一次性使用医疗用品销售；劳动防护用品生产；劳动防护用品销售；鞋制造；鞋帽批发；鞋帽零售（除依法须经批准的项目外，凭营业执照依法自主开展经营活动）。许可项目：第二类医疗器械生产；医用口罩生产；卫生用品和一次性使用医疗用品生产；货物进出口；技术进出口（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，具体经营项目以审批结果为准）。		
登记机关	浙江省义乌市后宅街道群英路66号（义乌市开泰工艺品厂内B栋北区1楼）（自主申报）		

2020年03月27日



国家企业信用信息公示系统网址：
<http://www.gsxt.gov.cn/>

市场主体应当于每年1月1日至6月30日通过
国家信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

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THE MINISTRY OF COMMERCE
OF CHINA

取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

企业 检索

企业名称 (中文)	企业名称 (英文)	产品类别	统一社会信用代码	国外注册认证情况
浙江紫家防护用品有限公司	Zhejiang The Purples Protective Products Co.,Ltd.	医用口罩	91330782MA2HR99B5W	欧盟CE

中国医药保健品进出口商会信息网 www.cccmhpie.org.cn/Pub/6325/176337.shtml 115%

企业名称 (中文)	企业名称 (英文)	产品类别	统一社会信用代码	国外注册认证情况
	Ningbo Shunkui Electronic Technology Co., Ltd.			
777 宁波天博急救用品有限公司	Ningbo Tianbo First Aid Product Co., Ltd.		91330212316977272W	欧盟CE
778 温州艾塔医疗科技有限公司	Wenzhou Aita Medical Technology Co., Ltd.		91330301MA2HB6MP7J	欧盟CE
779 怡康医疗科技(宁波)有限公司	Yikang Medical Technology(Ningbo) Co.,Ltd.		91330201MA2H45992X	欧盟CE
780 浙江邦好宁医药用品有限公司	Zhejiang Banghaoning Medical Supplies Co.,Ltd.		91330782712554175U	欧盟CE
781 浙江铁枫堂药业有限公司	Zhejiang Tiefengtang Pharmaceutical Co., Ltd.		91330382313556819C	欧盟CE
782 浙江中美日化有限公司	Zhejiang Wharney Daily Chemical Co.,Ltd.		913307037498414937	欧盟CE
783 浙江紫家防护用品有限公司	Zhejiang The Purples Protective Products Co.,Ltd.		91330782MA2HR99B5W	欧盟CE
784 重庆龙翼生物科技有限公司	Chongqing Longyi Biotechnology Co.Ltd		915001013050495573	欧盟CE
二、 医用防护服 Medical Protective Gowns				
1 稳健医疗用品股份有限公司			91440300723009295R	欧盟CE

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海关进出口货物收发货人备案回执

企业名称	浙江紫家防护用品有限公司
统一社会信用代码	91330782MA2HR99B5W
海关备案日期	2020 04 02
海关编码	3318960B53
检验检疫备案号	3362200450
有效期	长期



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://credit11.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。

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对外贸易经营者备案登记表

备案登记表编号: 04276781

统一社会信用代码: 91330782MA2HR99B5W
进出口企业代码:

经营者中文名称	浙江紫家防护用品有限公司		
经营者英文名称	Zhejiang The Purples Protective Products 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	浙江省义乌市后宅街道群英路66号(义乌市开泰工艺品厂内B栋北区1楼)(自主申报)		
经营场所(中文)	浙江省义乌市后宅街道群英路66号B栋北区1楼		
经营场所(英文)	1/F, North Zone, Building B, No.66, Qunying Road, Houzhai, Yiwu, Zhejiang Province		
联系电话		联系传真	
邮政编码	322000	电子邮箱	ZJSHITURK@163.com
工商登记注册日期	2020-3-27	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	谢江	有效证件号	362301197106150030
注册资金	壹亿元		(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/ 个体工商户负责人姓名		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户负责人签字、盖章。



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 浙江稠州商业银行 ZHEJIANG CHOUZHOU COMMERCIAL BANK	
基本存款账户信息	
浙江紫家防护用品有限公司	
账户名称:	15630012010090012420
账户号码:	浙江稠州商业银行股份有限公司义乌后宅支行
开户银行:	谢江
法定代表人: (单位负责人)	J3387022529301
基本存款账户编号:	
2020 04 01 年 月 日	

开票资料

单位名称: 浙江紫家防护用品有限公司

纳税人识别号: 91330782MA2HR99B5W

地址: 义乌市后宅街道群英路66号B栋北区1楼

开户行(全称): 浙江稠州商业银行股份有限公司义乌后宅支行

账号: 15630012010090012420

MASK SAMPLE



▲
Type I

MASK SAMPLE



▲
Type II

MASK SAMPLE



▲
Type IIR

MASK SAMPLE



▲
Non-medical