1. 生产批号：出口定批 20200215，有效期 20220214；GMDN/UMDNS 代码：12447；
   医用口罩产品编码：63079000；一箱 2000 只，毛重 9 公斤，净重 6.7 公斤；
   纸箱尺寸 520cm×390cm×350cm。
2. CE 注册备案证

www.llins-service.com
Llins, your trusted partner,
Representing you in EU !

Confirmation

of EU product notifications submitting

This is to confirm that according to Regulation (EU) 2017/745, Llins performed all notification duties and responsibilities as the European Authorized Representative (EC Rep) of:

MANUFACTURER: **Changzhou Shuangma Medical Devices Co., Ltd.**

ADDRESS: **San He Kou Development Zone, 213115 Zhenglu, Tianning Changzhou, Jiangsu, China**

as stipulated and demanded by the aforementioned regulation.

The manufacturer declares that the Medical device - Medical face mask complies with the regulation including all the general safety and performance requirements.

*This conformation will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EC Rep agreement.

13 March, 2020

LLINS SERVICE & CONSULTING GMBH
OBERE SEEGASSE 34/2
69124 HEIDELBERG

Dipl. Ing. J.F. REN
– on behalf of –
Llins Service & Consulting GmbH

Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124, Heidelberg, Germany
www.llins-service.com

3. 双马公司符合性声明

EC DECLARATION OF CONFORMITY

Name und Adresse des Herstellers: / Name and address of the manufacturer:	Changzhou Shuangma Medical Devices Co., Ltd. San He Kou Development Zone, Zhenglu, Tianning Changzhou, Jiangsu, China.213115
Bevollmächtigter der EG: / EC Authorized Representative:	Llins Service & Consulting GmbH Obere Seegasse 34/2, 69124, Heidelberg, Germany

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that

das Medizinprodukt: / the medical device:	Medizinische Gesichtsmasken / Medical Face mask Modell/ Model: Planar ear loop
UMDNS-Code: / UMDNS code:	12447
Standard: / Standard:	EN 14683:2019
Produktfotografie: / Product photograph	
Grundlegende UDI-DI: / Basic UDI-DI:	/
Handelsname: / Trade name:	/
der Klasse: / of class:	Class I nach Anhang VIII der Verordnung EU 2017/745 (MDR) / according to annex VIII of Regulation EU 2017/745(MDR)

Erfüllt die Bestimmungen der Verordnung EU 2017/745 (MDR). Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". / Meets the provisions of the Regulation EU 2017/745(MDR). The declaration is valid in connection with the "final inspection report" of the device.

Konformitätsbewertungsverfahren: / Conformity assessment procedure:	Annex II, Annex III of EU 2017/745
Die Konformitätserklärung ist gültig bis: / Declaration of Conformity is valid until: /	2021-03-10

changzhou, 2020-03-10
Ort, Datum / Place, date /

Xu aiping General Manger
Name und Funktion / Name and function

4. 医用口罩技术文档

CE

Medical face mask

Instruction for Use

[Product Name]
Medical face mask
[Model/Size]

Model: Planar ear loop

Size: 17.5CM*9.5CM

[Intended use]
The Medical Face Masks are intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. The main aim is to protect the patient against infectious germs. In addition, in certain situations the wearer should be protected against splashes of potentially contaminated liquids and viable particles.
[Contraindications]
People who are allergic to product materials.
[Directions for use]
1. Open the package, take out the mask and expand it longitudinally to form a space between the nose and mouth to make the breathing smooth.
2. Face the mask with light color, dark color and nose clip upward (a plastic strip).
3. After wearing the face, adjust the nose clip to make it have good tightness and prevent harmful substances in the air from leaking into the sealing place.
4. After use, it shall be discarded in the specified dirt box and treated in a unified way to avoid product reuse hazards and environmental pollution.
[Precautions]
1. Read the manual carefully before use;
2. This product is disposable, can not be washed and reused;
3. Do not use in sterile ward or invasive operating room;
4. It is forbidden to use the package if the seal is disconnected, damaged or beyond the validity period of the product.
[Package]
Plastic packaging bag，Single packing.
[Expiry]
2 years.
[Production Date]
Refer to the package label
[Storage conditions]

1. Products shall be protected from heavy pressure, direct sunlight and rain and snow during transportation;
2. It shall be stored in a ventilated, dry and non corrosive gas environment. Keep away from fire sources and inflammables.

[Sterilization Method]

None

[Symbol Description]


Caution, Indicates the need for the user to consult the instructions for use for important cautionary information, such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Authorized representative in the European Community, Indicates the Authorized representative in the European Community


CE Mark: conforms to essential requirements of the Medical Device Regulation 2017/745 (EU)


Date of manufacture, Indicates the date when the medical device was manufactured


Manufacturer, Indicates the medical device manufacturer, as defined in Medical Device Regulation 2017/745 (EU)


Use-by date, Indicates the date after which the medical device is not to be used


Do not re-use, indicates a medical device that is intended for one use, or for use on a single patient during a single procedure


Do not use if package is damaged, indicates a medical device that should not be used if the package has been damaged or opened

Non-sterile

Batch code, Indicates the manufacturer's batch code so that the batch or lot can be identified.


Fragile, handle with care, indicates a medical device that can be broken or damaged if not handled carefully.


Keep away from sunlight, indicates a medical device that needs protection from light
sources.

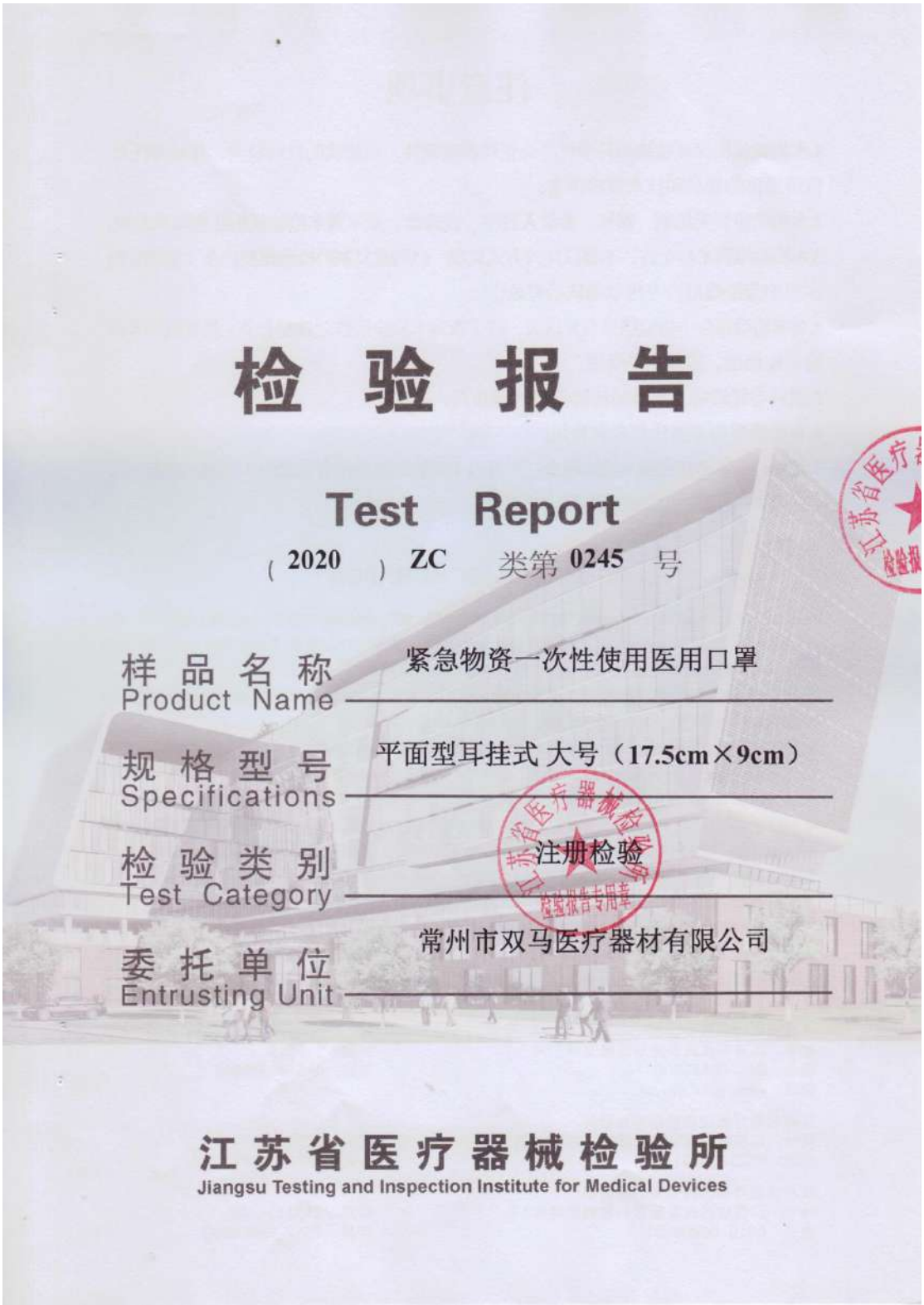

Keep dry, indicates a medical device that needs to be protected from moisture.

Name: Changzhou Shuangma Medical Devices Co., Ltd.
Add: San He Kou Development Zone, Zhenglu, Tianning Changzhou, Jiangsu, China.
Tel: 0086 519-88676588
www.shuangma-china.com

EC REP
Name: Llins Service & Consulting GmbH
Add: Obere Seegasse 34/2, 69124, Heidelberg, Germany
DIMDI Code: DE/0000048234
Email: info@llins-service.com
Tel: +49 175 4870 819

Prepared by	Audited by	Approved by
冯迎菊	[illegible]	徐爱萍
2020-03-10	2020-03-10	2020-03-10

5. 20200215 医用口罩检测报告（中文），注：中英文的医用口罩检测报告过几日上传。



检 验 报 告

Test Report

（2020）ZC 类第 0245 号

样品名称 Product Name：紧急物资一次性使用医用口罩

规格型号 Specifications：平面型耳挂式 大号（17.5cm×9cm）

检验类别 Test Category：注册检验

委托单位 Entrusting Unit：常州市双马医疗器材有限公司

江苏省医疗器械检验所

Jiangsu Testing and Inspection Institute for Medical Devices

江苏省医疗器械检验所
检验报告首页

报告编号：2020ZC0245　　首页1页 W1页 S1页 Z1页 共4页

样品名称	紧急物资一次性使用医用口罩		样品编号	SLZC2002257
	送样（√）	抽样（）		
商标	/		规格型号	平面型耳挂式 大号（17.5cm×9cm）
委托方	常州市双马医疗器材有限公司		检验类别	注册检验
委托方通讯地址	常州市天宁区郑陆镇三河口开发区		产品编号/批号	20200215
标示生产单位	常州市双马医疗器材有限公司		抽样单编号	/
受检单位	常州市双马医疗器材有限公司		生产日期	/
抽样单位	/		样品数量	200只
抽样地点	/		抽样基数	/
抽样日期	/		检验地点	本检验所试验室
收样日期	2020年2月27日		检验日期	2020年2月27日-2020年3月2日
检验项目	2.1-2.6			
检验依据	常州市双马医疗器材有限公司产品技术要求《紧急物资一次性使用医用口罩》			
检验结论	所检项目符合常州市双马医疗器材有限公司产品技术要求《紧急物资一次性使用医用口罩》规定的要求。 （检验报告专用章或检验单位公章） 签发日期 2020 年 3月 3日			
备注	1)报告中的“——”表示此项不适用，报告中“/”表示此项空白。 2)报告页眉中的“W”表示物理，“S”表示生物，“Z”表示照片。			

批准：[illegible]

职务：技术负责人

江苏省医疗器械检验所
检 验 报 告

报告编号：2020ZC0245　　W　共1页　第1页

序号	检验项目	条款	要求	检验结果 1#～3#	单项结论	备注
1	外观	2.1	口罩外观应整洁、形状完好，表面不得有破损、污渍。	符合要求	符合	/
2	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。	符合要求	符合	/
			长度：17.5cm±0.9cm	17.49cm～17.51cm		
			宽度：9cm±0.5cm	9.06cm～9.13cm		
3	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	符合	/
		2.3.2	鼻夹长度应不小于 8.0cm。	11.20cm～11.22cm		
4	口罩带	2.4.1	口罩带应戴取方便。	符合要求	符合	/
		2.4.2	每根口罩带与口罩体连接处的断裂强力应不小于 10N。	符合要求		
5	通气阻力	2.6	口罩两侧面进行气体交换的通气阻力应不大于 49Pa/cm²。	23.0Pa/cm²～23.8Pa/cm²	符合	/

检 验：汪翠萍　　审 核：秦黎

江苏省医疗器械检验所
检 验 报 告

报告编号：2020ZC0245　　S　　共 1 页　第 1 页

序号	检验项目	条款	要求	检验结果	单项结论	备注
1	细菌过滤效率（BFE）	2.5	口罩的细菌过滤效率应不小于95%。	样品 1：97.4% 样品 2：97.5% 样品 3：97.3%	符合	/
以下空白						

检 验：

审 核：

江苏省医疗器械检验所
检 验 报 告 照 片 页

报告编号：2020ZC0245　　Z 共 1 页　第 1 页

照片和说明
   
样品描述
/
型号规格或其它说明
产品型号规格为平面型耳挂式 大号（17.5cm×9cm）。

常州市食品药品监督检验中心

检 验 检 测 报 告

报告编号:CZ2020XS0037

检品名称： 一次性使用医用口罩

供样单位： 常州市双马医疗器材有限公司

委托单位： 常州市双马医疗器材有限公司

检验目的： 委托检验

常州市食品药品监督检验中心

检验检测报告

报告编号：CZ2020XS0037　　第 1 页　共 1 页

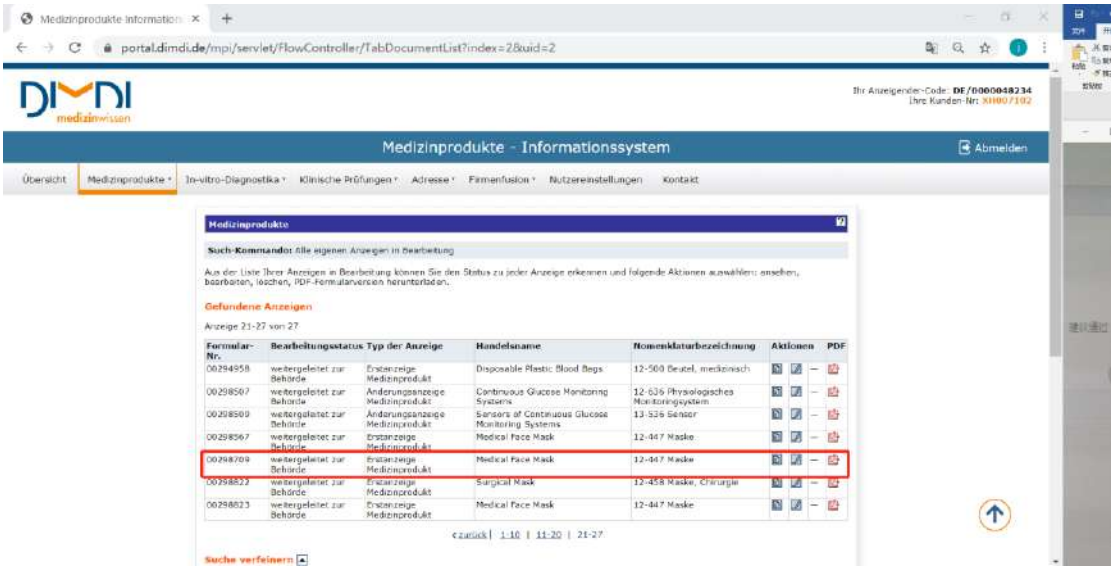
检品名称	一次性使用医用口罩	批　号	20200215
规　　格	17.5cm×9cm	包装规格	1个/袋
生产单位/产地	常州市双马医疗器材有限公司	检品数量	10袋
供样单位	常州市双马医疗器材有限公司	有 效 期	2年
委托单位	常州市双马医疗器材有限公司	联系电话	15161137112
检验项目	微生物指标	检验目的	委托检验
检验依据	YY/T0969-2013	收检日期	2020-02-20

检验项目	标准规定	检验结果
【微生物指标】		
细菌菌落总数	不得过100CFU/g	84CFU/g
大肠菌群	不得检出	未检出
绿脓杆菌	不得检出	未检出
金黄色葡萄球菌	不得检出	未检出
溶血性链球菌	不得检出	未检出
真菌	不得检出	未检出

---------（以下空白）---------

检验结论	本品按YY/T0969-2013检验上述项目，结果符合规定。		
授权签字人		签发日期	2020-02-27

6. CE 注册备案证如何查询：



二、关于医用口罩 FDA 出口说明

1．FDA 证书

ZERTIFIKAT ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ 認證證書 ◆ CERTIFICATE

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

CHANGZHOU SHUANGMA MEDICAL DEVICES CO., LTD
San He Kou Development Zone, Zhenglu Town, Tianning District
Changzhou, Jiangsu, 213115, CHINA
has completed the FDA Establishment Registration (as manufacturer , foreign exporter, contract manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications: SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.com

Owner/Operator Number: 10063032
Device Listing#:

Listing No	Code	Device Name
D375120	LYU	ACCESSORY, SURGICAL APPAREL (Isolation mask)

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

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

Sungo global service FDA

SUNGO
Executive Director
Issued: Mar. 16 2020
Cert. No.: 2007US077518
Expiration Date: Dec. 31 2020
CERTIFIED

SUNGO CHINA OFFICE Tel: 021-68828052 Email:Shage2008@126.com Website: www.sungoglobal.com
Add: 13th Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China

2．查询 FDA 证书网址

网址：https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm