Medical Product List

Isolation Gown

Product Photo	FOB Price:	MOQ:

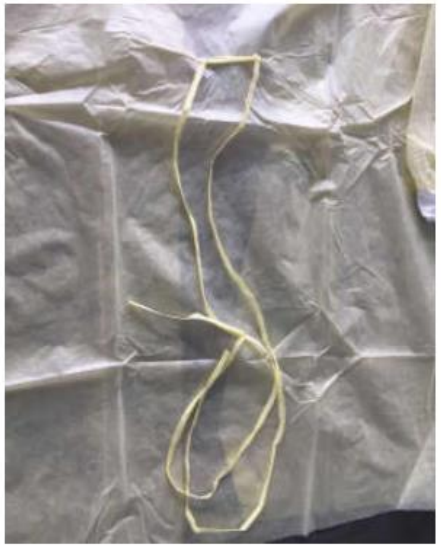
Description	Isolation Gown
Item	Specification
Gown Size(cm)	130*147
Material	Front chest and sleeve :17g SPP laminated with 15g PE Back panel: 17g SPP+15PE net weight:32g
Color	Yellow
Cuff	100% Polyester
Belt size(cm)	190
Packing /Ctn size	10pcs/bag, 10bags/carton /55*32*40cm G.W./N.W.:9.4/8.5Kgs
Approval:	CE

Product Photo

BACK PANEL

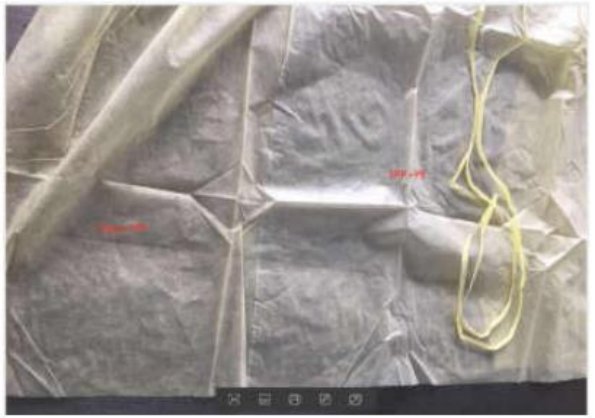
FRONT CHEST

CUFF



BELT

NECKLINE



MATERIAL

Isolation Gown

Product Photo	FOB Price:	MOQ:

Description	Isolation Gown
Item	Specification
Gown Size(cm)	132*157
Material	SMS 35gsm Anti-static net weight:35g
Color	Dark blue
Cuff	100% Polyester
Belt size(cm)	178
Packing /Ctn size	10pcs/bag, 10bags/carton /55*32*40cm.G.W./N.W.:11/10Kgs
Approval:	CE

Product Photo

BACK PANEL

FRONT CHEST

CUFF

NECKLINE

BELT

Certificate

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q6 18 03 87197 008

Holder of Certificate: **S.E.S Healthcare Products (Hefei) Co., Ltd.**
Feng Xia Road
Shuang Feng Development Zone
231131 Hefei
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
S.E.S Healthcare Products (Hefei) Co., Ltd.
Feng Xia Road, Shuang Feng Development Zone, 231131 Hefei, PEOPLE'S REPUBLIC OF CHINA

S.E.S Healthcare Products (Hefei) Co., Ltd.
Jinzang Road, Shuang Feng Development Zone, 231131 Hefei, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Surgical Gown, Surgical Drape, Surgical Kit, Surgical Table Cover, Surgical Mayo Cover**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1886505

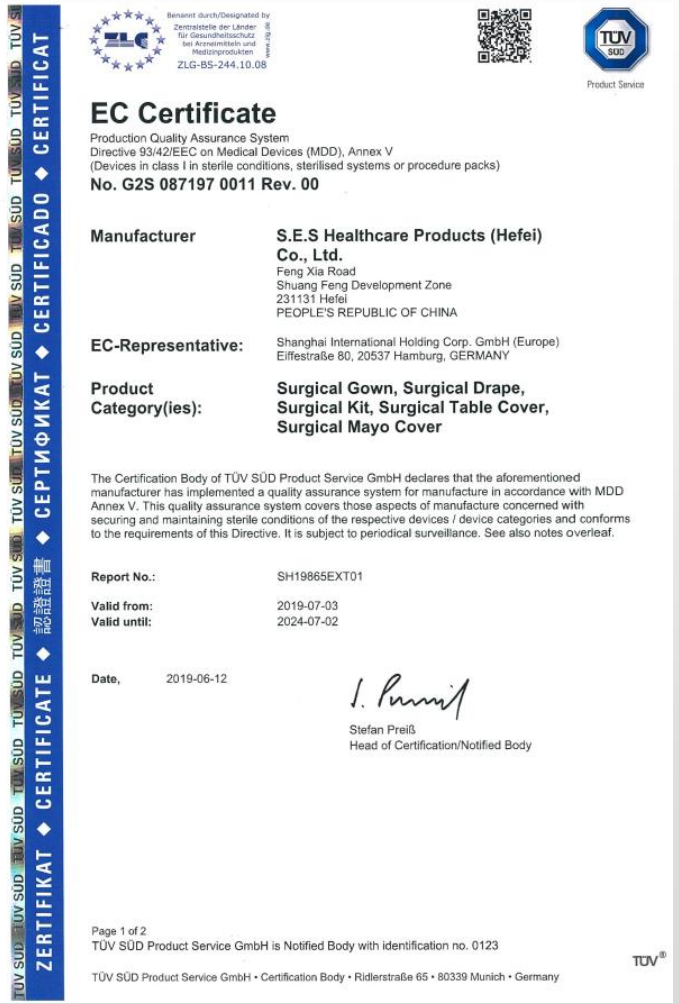
Valid from: 2018-06-29
Valid until: 2020-07-02

Date, 2018-06-29

Stefan Preiß

Page 1 of 1

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany



ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 087197 0011 Rev. 00

Manufacturer **S.E.S Healthcare Products (Hefei) Co., Ltd.**
Feng Xia Road
Shuang Feng Development Zone
231131 Hefei
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): **Surgical Gown, Surgical Drape, Surgical Kit, Surgical Table Cover, Surgical Mayo Cover**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH19865EXT01

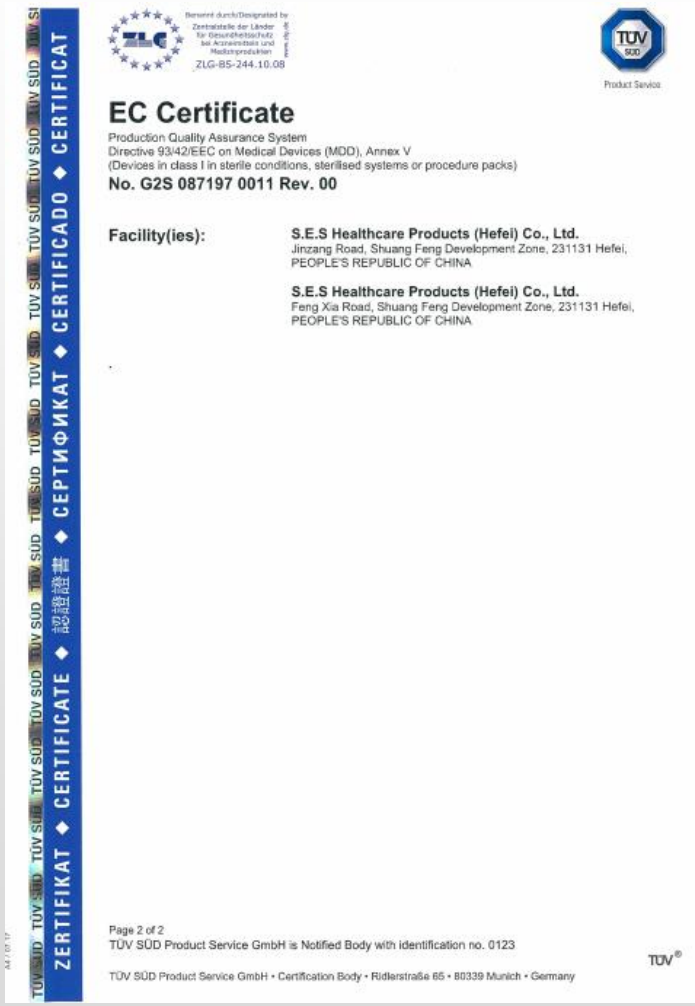
Valid from: 2019-07-03
Valid until: 2024-07-02

Date, 2019-06-12

Stefan Preiß
Head of Certification/Notified Body

Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 087197 0011 Rev. 00

Facility(ies):
S.E.S Healthcare Products (Hefei) Co., Ltd.
Jinzang Road, Shuang Feng Development Zone, 231131 Hefei, PEOPLE'S REPUBLIC OF CHINA

S.E.S Healthcare Products (Hefei) Co., Ltd.
Feng Xia Road, Shuang Feng Development Zone, 231131 Hefei, PEOPLE'S REPUBLIC OF CHINA

Page 2 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

KN95 MASK

Product Photo	FOB Price:	MOQ:

Description	KN95 MASK
	EN149：2001+A1：2009 Mask Size:13*14cm Ctn size:44.5*40*28cm G.W./N.W.:4.6/3.1Kgs Qty:50Pcs/ color box,9 boxes/Ctn
Approval:	CE, FDA

Product Photo

Certificate

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Form QAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 3Q200329B.SIM0026

Certificate's Holder: [redacted] China

Certification ECM Mark: Type Approved

Product: Respiratory- KN95 mask
Model(s): KN95A, KN95B, KN95C, KN95D, KN95E
Verification to: Standard: EN 149: 2001 + A1 2009

related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 29 March 2020

Expiry date: 28 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Badonni

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 +39 051 6705156 info@entecerma.it www.entecerma.it

CERTIFICATION OF REGISTRATION

This certifies that:

Sh, Shandong,

is registered and has listed the following medical device with the U.S. Food and Drug Administration :

Owner/Operator Number : 10064811

Listing Number: D380103

Product Code : MSH

Product : Respiratory-KN95 mask

Model(s) : KN95A

Date Of Registration Status: 2020

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp 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-holderd's device or establishment by the U.S. Food and Drug Administration. Registrar Corp 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. Registrar Corp is not affiliated with the U.S. Food and Drug Administration

Chief Engineer / Zacchio Lee

Issued: Mar. 27, 2020
Validity Period:2020-12-31

Web rep/www.fda.gov Tel 1-888-INF0-FDA(1-888-0332) E-mal vcrp@fda.gov

KN95 MASK

Product Photo	FOB Price:	MOQ:
	Description	KN95 MASK
	EN149：2001+A1：2009 FFP2 Mask Size:13*14cm 5Pcs/bag,size:15*16*1.5cm 10bag/box32*13*17cm 18box/ctn:66*55*40cm G.W./N.W.:9.3/8.3Kgs	
	Approval:	CE

Product Photo

Certificate

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 0P200310.HXE0W94

Technical Construction File no. TPZJ200309/21985

Certificate's Holder: Hangzhou Xiangwai Enviromental Protetion Technology Co., Ltd.
Room 406, Building 3, Shidao Science and Technology Park, Ge Xiang Village, Cangqian Street, Yuhang District, Hangzhou City, Zhejiang

Manufacturer: Zhangjiang Ampson Medical Equipment Co., Ltd.
Haitang Industrial Park, Tangqiao Street, Haiyan City, Jiaxing City, Zhejiang Province

Certification ECM Mark: Type Approved

Product: Respiratory protective equipment — Non-powered air-purifying particle respirator

Model(s): P8001B

Verification to: Standard: EN 149:2001+A1:2009

related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it
This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking: We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE Marking Certification Procedure through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of issue 10 March 2020 — Chief Manager Michele Montag

Expiry date 09 March 2025 — Deputy Manager Amanda Payne

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

检验报告

IMA 180011112242 — CNAS 中国认可 国际互认 检测 TESTING CNAS L6780

检 验 报 告

TEST REPORT

扫一扫关注我们 扫一扫查询真伪

报告编号 REPORT NO.	国纺委字第 YJ202000773 号
产品名称 NAME OF SAMPLE	口罩 8001B
委托单位 CUSTOMER	浙江安普森医疗器械有限公司
检验类别 TEST CATEGORY	委托检验

浙江省轻工业品质量检验研究院
（浙江省纺织测试研究院）
Zhejiang Light Industrial Products Inspection and Research Institute
国家纺织服装产品质量监督检验中心（浙江）
National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心（浙江）

检验报告

国纺委字第 YJ202000773 号 第 1 页 共 3 页

委托单位名称 Name of Customer	浙江安普森医疗器械有限公司	地 址 Address	——
生产单位 Manufacturer	——	地 址 Address	——
样品信息 Sample information	样品名称 Name of sample：口罩 8001B 样品特性 Characteristics：白色 商标 Trademark：—— 规格/号型 Specification/model：—— 等 级 Level：KN95 安全技术类别 Category of safety specification：—— 样品款号/货号 Art. No.：——		
以上为客供信息（Above-mentioned information by Customer-supplied）			
来样方式 The sent way of sample	快递	样品数量 Sample quantity	21 只
送检日期 Receiving Date of Sample	2020-02-28	检测类别 Test Category	委托检验
判定依据 RatingRequirements	GB 2626-2006		

检测结论/Test Summary：

实测结果详见附页。

检验报告专用章/Test Seal

批准日期/ Date of Approval：2020-02-28

备 注 Remarks	样品未经预处理。

签 发：
Approved by

检验报告

国纺委字第 YJ202000773 号 第 2 页 共 3 页

序号	检测项目		检测方法	单位	标准要求（KN95）	实测值	单项评价	结果备注
1	过滤效率		GB 2626-2006 6.3	%	≥95.0	96.9	符合	——
2	呼吸阻力	吸气阻力	GB 2626-2006 6.5 6.6	Pa	≤350	67.3	符合	——
		呼气阻力		Pa	≤250	55.8		

Disposable mask

Product Photo	FOB Price:	MOQ:
	Description	Disposable mask
	EN 149:2001 Volume (Carton) ：64.5*45*57CM Number：50pcs/box , 50boxes/carton Weight：11.5kg	
	Approval:	CE,FDA

Certificate

Review Report –审查报告–검토 보고서– Rapport d'Evaluation

Form QAT_10-M04, version 00, effective since March 6th, 2020

CE Documentation Review

No. 0H200325M..JYM0271

Holder:	JiangSu Yaohua Medical Device Technology Co., Ltd. Yaohua Road, Houxiang, Danbei Town, Danyang City, Jiangsu Province, China
Review goal:	Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII
Product:	Disposable Medical Face Mask (Not Sterile)
Model(s):	175 mm x 95 mm
Classification:	Class I (Not Sterile) (accordingly to the Manufacturer's declaration)
Review output:	This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 25 March 2020
Approver
ECM Service Director
Luca Regonini

Expiry date 24 March 2025
Technical Expert
Amanda Payne

Ente Certificazione Macchine
Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.0516705141 🖷 +39.0516705156 ✉ info@entecerma.it 🌍 www.entecerma.it

CERTIFICATE OF REGISTRATION 2020

This Certifies that:
At The Address Stated Below Has Completed U.S. FOOD And DRUG Administration Medical Device Registration Through Wayborn.

JIANGSU YAOHUA MEDICAL DEVICE TECHNOLOGY CO., LTD
Yaohua Road, Houxiang, Danbei Town, Danyang City, Jiangsu, 212312, CHINA

Owner/Operator Number: 10064654
Product Name: FACE MASK
Product Listing Number: See Annex page

FDA

This Certificate affirms that Wayborn Quality & Technology Services has verified that the above stated facility is registered with the US Food & Drug Administration, on the date stated above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. Wayborn Quality & Technology Services assume no liability to any person or entity in connection with the foregoing. Wayborn Quality & Technology Services is a private registration agent and is not affiliated with the US Food and Drug Administration.

Crane Yu
Director
March 30, 2020

The FDA annual establishment registration fee must be paid between Oct. 1 and Dec. 31 of every year.
Web: http://www.fda.gov

Certificate

171021110579

检验检测报告

TEST REPORT

STFWT20201749

产品名称 Product Name：一次性口罩

委托单位 Trust Unit：江苏耀华医疗器械科技有限公司

生产单位 Manufacturer：江苏耀华医疗器械科技有限公司

检验检测类别 Test Category：委托送样检验

江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

检 验 检 测 报 告

Test Report

防伪查询

STFWT20201749

共 4 页 第 1 页
Page 1 of 4

产品名称 Product Name	一次性口罩	规格型号 Specification Type	175×95mm-3P
		商 标 Trademark	CreeK
委托单位 Trust Unit	江苏耀华医疗器械科技有限公司	电 话 Tel	15862962510
生产单位 Manufacturer	江苏耀华医疗器械科技有限公司	样品等级 Sample Grade	——
样品数量 Sample Quantity	60 个	送样日期 Sample Receiving Date	2020-02-24
检验检测类别 Test Category	委托送样检验	批号/编号 Serial Number	2002P020
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	GB/T 32610-2016《日常防护型口罩技术规范》		
检验检测结论 Test Conclusion	检验检测结果见第二页	签发日期：2020-03-09 SignatuimDate	
备 注 Remarks	本报告仅对来样负责。		

批 准：Approver　　审 核：Examiner　　主 检：Majortester

检 验 检 测 结 果

Testing Results

STFWT20201749

共 4 页 第 2 页
Page 2 of 4

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	可分解致癌芳香胺染料：4-氨基联苯	mg/kg	应禁用	仅考核染色和印花部分，不测此项	——
	联苯胺		应禁用		
	4-氯邻甲基苯胺		应禁用		
	2-萘胺		应禁用		
	邻氨基偶氮甲苯		应禁用		
	5-硝基-邻甲苯胺		应禁用		
	对氯苯胺		应禁用		
	2,4-二氨基苯甲醚		应禁用		
	4,4'-二氨基二苯甲烷		应禁用		
	3,3'-二氯联苯胺		应禁用		
	3,3'-二甲氧基联苯胺		应禁用		
	3,3'-二甲基苯胺		应禁用		
	3,3'-二甲基-4,4'-二氨基二苯甲烷		应禁用		
	2-甲氧基-5-甲基苯胺		应禁用		
	4,4'-亚甲基-二-（2-氯苯胺）		应禁用		
	4,4'-二氨基二苯醚		应禁用		
	4,4'-二氨基二苯硫醚		应禁用		
	邻甲苯胺		应禁用		
	2,4-二氨基甲苯		应禁用		
	2,4,5-三甲基苯胺		应禁用		
	邻氨基苯甲醚		应禁用		
	2,6-二甲基苯胺		应禁用		
	2,4-二甲基苯胺		应禁用		
	4-氨基偶氮苯		应禁用		

Silicone Mask

Product Photo	FOB Price:	MOQ:
	Description	Silicone Mask
	Replaceable filter element Recycling,environmentally healthy living ***Strap sheath protction adjustable length*** freely adjust to the optimal length,the silicone sheath will not be worn for a long time ***Soft silicone*** Soft and comfortable,it won't hurt your face.	
	Approval:	

Product Photo

Replaceable filter element

Recycling, environmentally healthy living

Strap sheath protection adjustable length

Freely adjust to the optimal length, the silicone sheath will not be worn for a long time

Soft silicone

Soft and comfortable, it won't hurt your face