



ZHEJIANG LEO MEDICAL EQUIPMENT CO., LTD.





LEO
MEDICAL

Company Introduction

Mask Production

Mask Specifications





LEO
MEDICAL

Company Introduction



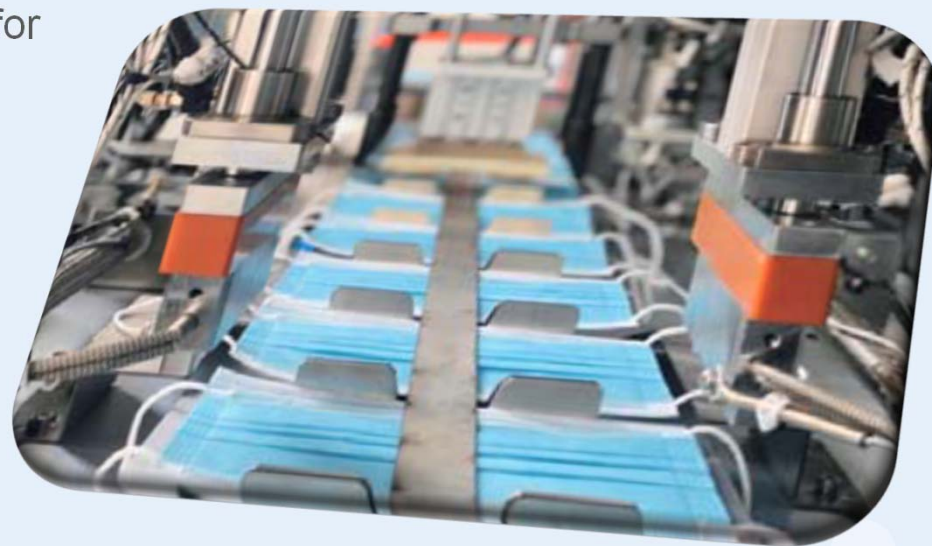


About LEO MEDICAL

Zhejiang LEO Medical Equipment Co., Ltd.,

a wholly-owned subsidiary of LEO GROUP CO.,LTD. (SZ 002131) is specialized in daily protective mask, disposable surgical mask, medical equipment manufacturing. The construction area is about 5,000m², and class 100,000 clean workshop remain constant temperature and humidity. A total of 10 automatic production lines for production of masks, with a daily production capacity of 1 million masks.

The products have obtained ISO 9001: 2015, FDA, CE and other international certifications for exporting, which can meet foreign demand and export to overseas.





Business license

for protective masks, medical masks and other Type-II medical materials

License

医疗器械生产许可证

许可证编号：浙食药监械生产许 20200094 号

企业名称：浙江利欧医疗器械有限公司 生产地址：浙江省台州市温岭市东部新区第四街 2 号

法定代表人：顾士富 生产范围：II 类:14-14-医护人员防护用品,

企业负责人：李治站

住 所：浙江省台州市温岭市东部新区第四街 2 号
(七号厂房一楼西侧) 发证部门：浙江省药品监督管理局

有效期限：至 2020 年 10 月 1 日 发证日期：2020 年 10 月 3 日



国家食品药品监督管理总局制

State Manufacturing License

for protective masks, medical masks and other Type-II medical materials



LEO
MEDICAL

Mask Production





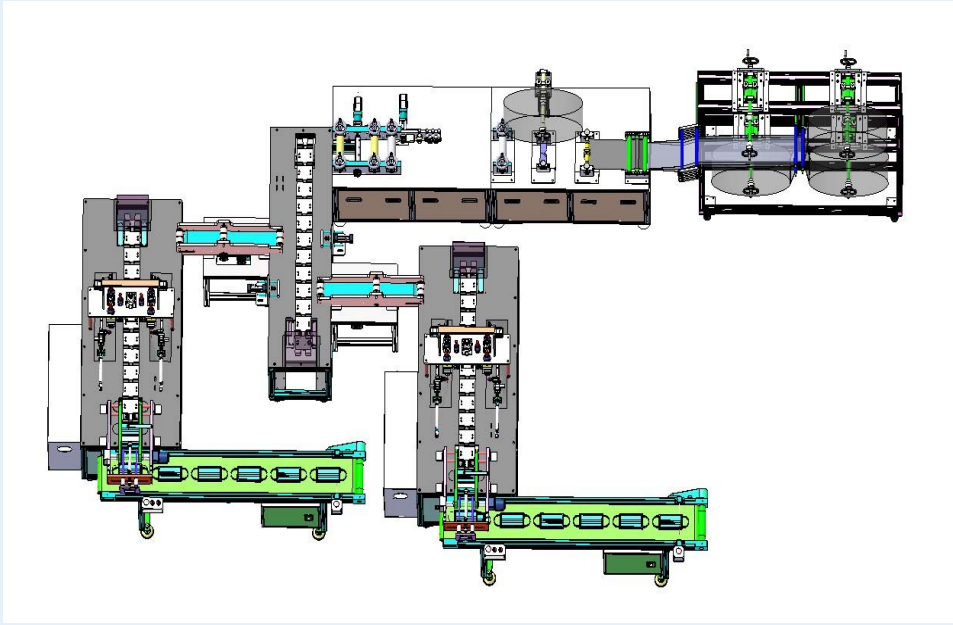
Production of Masks

The company has functional departments such as QM Dept. Production Dept. R&D Dept., Purchasing Dept., and Marketing Dept. etc., with sound organizational structure and complete staffing.





Production Procedures

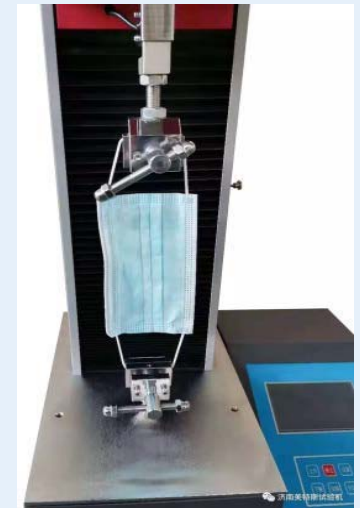


Testing

Detection technology

We have established a mask inspection standard system to inspect appearance inspection, structure and size, nose clips, mask bands, bacterial filtration rate, ventilation resistance, microbial indicators, and ethylene oxide residue detection.

The R&D and Technology Dept. will test the main filter materials based on the intended use and scope of the product, and other core materials for testing, data comparison, screening of different types of materials, and analysis of mask manufacturing processes to ensure that masks can be used safely after leaving the factory.





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Mask Specifications





MASK-01 Specifications



Product Name		Daily Protective Mask
Model		MASK-01
Size		17.5cm×9.5cm
Filtration	BFE	—
	PFE	Salt ≥90%; Oil ≥80%
Protective Effect		≥65%
Airway Resistance	Inhalation	≤175pa
	Expiration	≤145pa
Breathability		—
Sterilization Type		Non-sterile
Packaging Quantity		50Pcs/Box
Packaging Size		205×100×90mm
Shipping Package Quantity		20Box/Carton
Shipping Package Size		515×420×187.5mm
Weight		4.7kg

MASK-01 Certificate

Certificate of Compliance

No. 3F200313.ZLMU084



Certificate's Holder: Zhejiang LEO Medical Equipment Co., Ltd.
No.2, 4th Street, East Industry Center, Wenling City, Zhejiang Province, P.R. China.

Certification ECM Mark:  Type Approved

Product: Daily Protective Mask
Model(s): MASK-01

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 13 March 2020

Expiry date 12 March 2025

Service Manager
Luca Bedonni

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



Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

ZHEJIANG LEO MEDICAL EQUIPMENT CO.,LTD.
No.2,4th Street, East New District, Wenling City, West of the first floor
of No.7 factory building Taizhou, Zhejiang, 317500, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10063826



Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D377208	KHA	MASK, SCAVENGING	Daily Protective Mask Mask-01

CCT 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. CCT 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. CCT 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. CCT is not affiliated with the U.S. Food and Drug Administration.



Chief engineer
Issued: 03/20/2020
Expiration Date: 12/31/2020



Shenzhen CCT Testing Technology Co., Ltd.
W: www.fda-test.com E: fda@fda-test.com
T: 400-8788-298 T: 86-755-30916737
Web: <http://www.fda.gov> Tel: 1-888-NFO-FDA (1-888-463-6332) e-mail: webmail@cc.fda.gov



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(2018) 第1111号



中国认可
五星认证
TESTING
CNAS L6780

检验报告 TEST REPORT



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报告编号
REPORT NO. 国统委字第 Y1202004231 号

产品名称
NAME OF SAMPLE 一次性使用平面口罩

委托单位
CUSTOMER 浙江利欧医疗器械有限公司

检验类别
TEST CATEGORY 委托检验

浙江省轻工业产品质量检验研究院
(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)



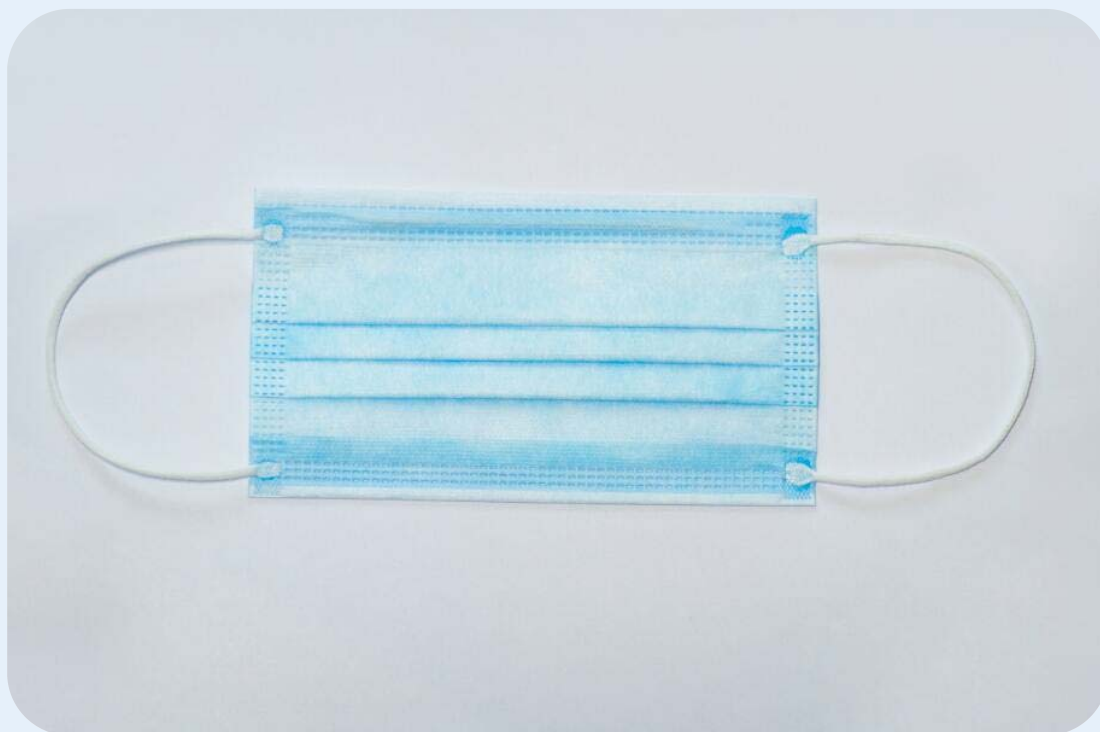
LY95 Specifications



Product Name		Disposable Face Mask
Model		LY95
Size		17.5cm×9.5cm
Filtration	BFE	≥95%
	PFE	—
Protective Effect		—
Airway Resistance	Inhalation	—
	Expiration	—
Breathability		≤49pa/cm ²
Sterilization Type		Non-sterile Aseptic
Packaging Quantity		50Pcs/Box
Packaging Size		205×100×90mm
Shipping Package Quantity		20Box/Carton
Shipping Package Size		515×420×187.5mm
Weight		4.7kg



LY95 Certificate



DECLARATION OF CONFORMITY ACCORDING TO THE REGULATION (EU) 2017/745



File. No.: C2004021550C

Produzent	Zhejiang LEO Medical Equipment Co., Ltd No.2, 4th Street, East Industrial Center, Wen Ling City, Zhejiang Province, P.R.C, 317511
Produkt	Disposable Face Mask
Model	LY95
Class	Class I medical device according to Annex VIII of Regulation (EU) 2017/745
Manufacturer Date	Mar 2020
European Authorised Representitive	3A Inno UG(haftungsbeschränkt) Eisfelder Str. 12, 96450, Coburg, Germany Contact: Xiurong Cai Email: 3ainnoug@gmail.com
Harmonised Standard which Comply With	EN 14683:2019 Medical face masks. Requirements and test methods Type I

The manufacturer declares under his sole responsibility that the above product under normal conditions of use and determined by the manufacturers Conditions is secure and all necessary legal conditions and Requirements fulfilled. The product is a medical device that is unique Use is intended and only corresponds to the manufacturer's instructions.

The manufacturer declares that he has taken all necessary measures to ensure that the Conformity of the products placed on the market with the technical documentation and ensure the basic requirements for this type of product.



ISSUED DATE: 02 APR 2020
EXPIRED DATE: 01 APR 2021



KN95/FFP2 Specifications



Product Name		KN95/FFP2	
Model		0302	0303
Size		14.5cm×8.5cm	15.5cm×10.5cm
Filtration	BFE	—	—
	PFE	≥95%	≥95%
Protective Effect		—	—
Airway Resistance	Inhalation	≤350pa	≤350pa
	Expiration	≤250pa	≤250pa
Packaging Quantity		20Pcs/Box	20Pcs/Box
Packaging Size		180×140×70mm	180×140×70mm
Shipping Package Quantity		50Box/Carton	50Box/Carton
Shipping Package Size		370×715×360mm	370×715×360mm



MASK01s Specifications



Product Name		Children Daily Protective Mask
Model		MASK01s
Size		14.5cm×9.5cm
Filtration	BFE	—
	PFE	—
Protective Effect		≥65%
Airway Resistance	Inhalation	—
	Expiration	—
Packaging Quantity		50Pcs/Box
Packaging Size		205×100×90mm
Shipping Package Quantity		20Box/Carton
Shipping Package Size		515×420×187.5mm



LY87-1 Specifications



Product Name	Goggle
Model	LY87-1
Standard Size	15*7.5*7mm
Executive Standard	GB 14866-2006
Diopter	($_{-0.07}^{+0.05}$)D
Prism	$\leq 0.125 \Delta$
Visible Light Transmittance	> 0.89
Impact Resistance	No Damage or Deformation
Heat Resistance	No Abnormality
Wear Resistance	No Oxidation of Metal Parts
Organic Mirror Surface Wear Resistance	Wear Rate H < 8%
High-speed Particle Impact Resistance	No Damage or Deformation
Protective Properties of Molten Metal and Hot Solids	No Adhesion or Breakage of Molten Metal
Chemical Mist Protection Performance	Test Paper without Color Spots
Dust Protection Performance	Reflectance Ratio > 80%
Irritation Gas Protection Performance	Test Paper without Color Spots
Packaging Quantity	10pcs/box
Packaging Size	76*34.5**44.5mm
Shipping Package Quantity	20box/Carton
Weight	18kg



LY87-1 Certificate

شهادة - Certificat - 증명서 - 證明書 - Сертификат

Form QAT_10-M04, version 00, effective since March 25th, 2020

Certificate of Compliance



No. 3F200409.ZLMTU64

Certificate's Holder: Zhejiang LEO Medical Equipment Co., Ltd.
No.2, 4th Street, East Industry Center, Wenling City, Zhejiang Province, P.R. China.

Certification ECM Mark:



Product: Goggles
Model(s): LY87-1

Verification to: Standard: EN 166:2001
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:



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: 07 April 2020

Expiry date: 06 April 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Badonni

Ente Certificazione Macchine Srl

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Fiscal Year 2020

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Shenzhen CCT Testing Technology Co., Ltd. 

Owner/Operator Number: 10063826

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D377208	KHA	MASK, SCAVENGING	Daily Protective Mask Mask-01
D385770	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydratric eyewear)	Goggles,LY87-1

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Shenzhen CCT Testing Technology Co., Ltd.
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Chief engineer
Issued: 03/20/2020
Expiration Date: 12/31/2020



Web: http://www.tta.gov.cn Tel: 1-800-INFO-FDA (1-800-464-6337) e-mail: wzhenshi@cct-test.com



THANK YOU

