

TAPABOCAS

3 CAPAS

USO MÉDICO



CERTIFICATE CE 802764619081
Shelf life: 2 years. Executive standard: GB/T 32610-2016
Hecho en China / Made in China

IMPORTADO CERTIFICADO



Certificado CE "Conformité Européene" No. 802764619081
NORMA TÉCNICA APLICADA NTC 1733

CLIP DE NARIZ:
Aluminio con revestimiento



Termosellado

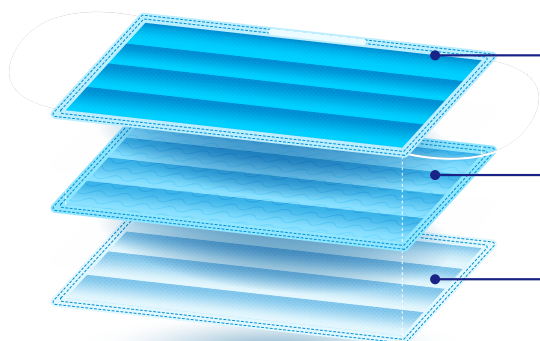
Bandas de caucho: aseguran
que el tapabocas se ajuste
perfectamente a ambos lados.

COMPOSICIÓN

3 CAPAS

Las cuales brindan mayor protección
evitando el ingreso de partículas.

- Anti polvo
- Anti fluidos
- Cómodo al respirar
- Protege contra salpicaduras



1 65% Filtro de tela no tejida (PP) - 30gsm

2 35% Filtro Meltblown - 25gsm

3 Capa interna: 30 gr. de tela no tejida.
Textura suave que evita irritaciones
en la piel

CARACTERÍSTICAS Y BENEFICIOS:

- Procesado en lugar limpio y empaquetada para reducir partículas.
- El material de la máscara está compuesto de polímero combinado PP, el cual es libre de pelusas y capas de superficie hipoalergénicas suaves que previene la irritación de la piel y los problemas de alergia.
- Embalaje en bolsas para mayor higiene.
- La unión ultrasónica garantiza una máscara más limpia al reducir la contaminación y la desgasificación.
- Tamaño comodo (200 mm) proporciona la máxima cobertura facial y reduce la piel expuesta.
- Se recomienda uso maximo de 4 hrs

ESPECIFICACIONES TÉCNICAS:

- Dimensión de máscara disponible en 200 mm x 90 mm.
- 65% Filtro tela no tejida (PP) - 30gsm
- 35% Filtro Meltblown- 25gsm
- CLIP DE NARIZ: Aluminio con revestimiento
- BANDAS OREJAS: Bandas elásticas ajustables.

RENDIMIENTO MÁSCARA:

- EFICACIA DE FILTRACIÓN BACTERIANA (EFB) - $\geq 95\%$
- RESISTENCIA A LA INHALACIÓN (Pa) - (REQUISITO ESTÁNDAR ≤ 175)
RESULTADO: NO TRATAMIENTO 136.5 / 135.7 - EXITOSO
TRATAMIENTO PREVIO 134.2 / 131.8 - EXITOSO
- RESISTENCIA A LA EXHALACIÓN (Pa) - (REQUISITO ESTÁNDAR ≤ 145)
- RESULTADO: NO TRATAMIENTO 124.7 / 125.6 - EXITOSO
TRATAMIENTO PREVIO 123.1 / 123.8 - EXITOSO

VIDA ÚTIL Y ALMACENAMIENTO:

- 2 años desde la fecha de fabricación
- Guarde los respiradores en su embalaje original, lejos de áreas contaminadas, polvo, luz solar, temperaturas extremas, humedad excesiva y productos químicos nocivos.
- Almacene en temperaturas entre -4°F (-20°C) y $+86^{\circ}\text{F}$ ($+30^{\circ}\text{C}$) y que no exceda el 80% de HR.

EMPAQUE:



合格证 CERTIFICATION	
产品名称 Product Name	一次性使用医用外科口罩 Disposable Surgical Face Mask
规格 Specification	17.5cm x 9.5cm
执行标准 Execution Standard	YY 0469-2011
原材料 Material	无纺布65%, 熔喷布35% 65% Nonwoven Fabric, 35% Melt-Blown Fabric
生产批号 Batch No.	LOT: 20051104
生产日期 Manufacture Date	2020/06/11
有效期 Expiry Date	两年 2 Years
注册证编号 Registration No.	鲁械注准20202140004
生产许可证编号 Production License No.	鲁食药监械生产许20140003号
厂商名称 Manufacturer	LUSHIYAO JIANYI SHENGZHONGYUAN Shandong Zhishi Pharmaceutical Group Co., Ltd.
厂商地址 Address	山东单县经济技术开发区 Shandong Single County Economic and Technological Development Zone, Shou County, Heze City, Shandong Province, China. 274300

APROBACIONES Y NORMAS:

EXECUTIVE STANDARD YY0469-2011

FDA

EC DECLARATION OF CONFORMITY

SGS TEST REPORT

INVIMA


Fiscal Year 2020
CERTIFICATION OF FDA REGISTRATION

This certifies that:

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

Owner/Operator Number: 10063404

Device Listing:

Listing No.	Code	Device Name	Proprietary Name
D376257	LYU	ACCESSORY, SURGICAL APPAREL	FACE MASK TD100, TD301, TD301, TD401, TD501, TD601, TD701, TD801, TD901, TD901 Protection Mask, KN95-01, KN95-02, KN95-03, KN95-04, KN95-05, KN95-06, KN95-07, KN95-08, KN95-09

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 expiration 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 807.33, "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.

Signature: 
Chief engineer
Issued: 03/29/2020
Expiration Date: 12/31/2020

Steven White
Date of Issue: March 23, 2020
Expiry Date: March 22, 2025

Signature: 
Chief engineer
Issued: 03/29/2020
Expiration Date: 12/31/2020

Signature: 
Chief engineer
Issued: 03/29/2020
Expiration Date: 12/31/2020


CERTIFICATE OF CONFORMITY
Certificate No.: VIC200323-CGT-4258

The Certification Body of

VIC TESTING AND CERTIFICATION LTD

Certifies that

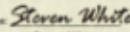
Applicant:

Manufacturer:

Product: FACE MASK
Class: FFP2
Model No.: TD101, TD201, TD301, TD401, TD501, TD601, TD701, TD801, TD901
Report No.: VIC200321-GTD01-CE-S

Complies with the requirements of the Regulation (EU)2016/425 Personal Protective Equipment (PPE). The submitted products have been tested by us and found in compliance with the following European Standards:
EN 149:2001+A1:2009.

This certificate of conformity is based on an evaluation of a sample of the above mentioned products. It does not imply an assessment of the whole production. The CE marking as shown below can be affixed on the product after preparation of necessary technical documentation.

Signature: 
Steven White
Date of Issue: March 23, 2020
Expiry Date: March 22, 2025


VIC
VIC TESTING AND CERTIFICATION LTD
AAA CHASE BUSINESS CENTRE (CHD) 15-41 CHASE ROAD LONDON, N14 6SP, UK
Email: info@vic-testing.com Website: www.vic-testing.com


Certificate of Registration
兹证明

广东途达医疗器械有限公司

地址

恩平市恩城街道恩洲工业大道南 27 号厂房一四楼

的质量管理体系适用于

血氧测定仪、血糖仪、血压计、热源测温仪、红外线测温仪、
防尘口罩、一次性口罩、防护口罩、医用外科口罩、
医用防护服、医用防护面罩的研发、生产和销售

经美国国际标准管理局审查注册符合

ISO9001: 2015

本注册要求组织按照上述标准保持其质量管理体系，并由 ISA 进行监督。
本证书在 www.asia-isa.com 网上不能查询，则为无效证书或已经撤销认证资格。

证书编号: ISA/HK/200405 认证周期至: 2023 年 04 月 06 日
发证日期: 2020 年 04 月 07 日 证书有效期至: 2021 年 04 月 06 日

Signed by: 





Certificate of Registration
This is to Certify that the Quality Management System of

Address

applicable to

Blood oximeter, Glucose meter, Blood pressure meter, Heat source thermometer, Infrared thermometer, Dust mask, Disposable mask, Respirators, Surgical mask, Medical protective clothing, Research and development of medical protective mask, Production and marketing

has been assessed and registered by International Standards Authority, Inc. against the provisions of

ISO9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by ISA.
www.asia-isa.com Cannot inquire, is the invalid certificate or the rescission qualifications.

Certificate Number: ISA/HK/200445 Authentication Cycle: 06 Apr 2023
Issued Date: 07 Apr 2020 Certificate Valid Until: 06 Apr 2021

Signed by: 




TEST REPORT:



检测报告

TEST REPORT

委托方 广东途达医疗器械有限公司
Commissioned by 广东途达医疗器械有限公司
生产单位 广东途达医疗器械有限公司
Factory 广东途达医疗器械有限公司
样品名称 一次性口罩 (Face Mask)
Name of Sample 广东途达医疗器械有限公司
型号规格 TD101
Type, Specification 广东途达医疗器械有限公司
检测类别 委托检测 Commission
Testing Purpose 广东途达医疗器械有限公司



广东产品质量监督检验研究院
GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION

广东产品质量监督检验研究院
GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION

检测报告

TEST REPORT

报告编号 Security Code: MC56628

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样品名称 Name of Sample	一次性口罩 (Face Mask)		样品编号 Sample number	YF220/015221
	送样 (✓) Sending	抽样 (✓) Sampling		
商标 Trade mark	---		型号规格 Type, Specification	TD101
委托方 Commissioned by	广东途达医疗器械有限公司		检测类别 Testing Purpose	委托检测 Commission
委托方地址 Address of client	恩平市恩城街道恩州工业大道南 27 号 4th floor, Factory Building 1, No. 27, Enzhou South Industrial Avenue, Encheng Street, Enping City		产品编号/批号 Product No./batch No	---
生产单位 Factory	广东途达医疗器械有限公司		抽样编号 Sampling lot No	---
受检单位 Inspected unit	---		生产日期 Date of manufacture	---
抽样单位 Sampling unit	---		样品数量 Quantity of sample	20 (个) 26 (Piece)
抽样地点 Location of sampling	---		抽样基数 Basic quantity of sampling	---
抽样日期 Date of sampling	---		检验地点 Location of testing	本部实验室 Laboratory
收样日期 Date of receiving	2020-04-29		检验日期 Date of testing	2020-04-29 ~ 2020-05-14
检测依据 Testing reference	GB/T 20810-2016 《日常防护型口罩技术规范》 GB/T 20810-2016 Technical specification of daily protective mask			
判定依据 Judging reference	---			
检测结论 Remarks	见检测结果。 Test results are attached as below.  Official testing stamp of the Institute 签发日期 Date of issue: 2020-05-14			
备注 Notes	报告中的 "—" 表示此项目不适用, 报告中 "✓" 表示此项目合格, "Q1" 表示此项目不合格。 "—" in the report indicates that this item is not applicable, and "✓" in the report indicates that this item is Pass, and "Q1" in the report indicates that this item is Fail.			

批准: 胡晓冬 审核: 王 主检: 张城

检测报告

TEST REPORT

No. FZ2015221

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序号 No.	检测项目[单位] Test item[Unit]	标准条款 Standard terms	标准要求 Standard requirements	检测结果 Result	单项结论 Conclusion	备注 Notes
1	吸气阻力[Pa] Inhale resistance (Pa)	5.3	≤175	未预处理 Untreated	136.5	合格 Pass
				预处理 Treated	135.7	
				未预处理 Untreated	134.2	
				预处理 Treated	131.8	
2	呼气阻力[Pa] Exhalation resistance (Pa)	5.3	≤145	未预处理 Untreated	124.7	合格 Pass
				预处理 Treated	125.6	
				未预处理 Untreated	123.1	
				预处理 Treated	123.8	
3	过滤效率[%] Filtration efficiency (%)	5.4	盐性介质 Salt Media: III ≥ 90	最小值 Minimum value: 99.5	合格 Pass	/

