
[redacted]
MEDICAL

N95 (FFP2 & FFP3), KN95 Respirators, 3-Ply Masks

Use of respirators approved under standards used in other countries that are similar to NIOSH-approved N95 respirators

“Other countries approve respirators for occupational use and approve respirators to these standards. These products are evaluated using some methods similar to those used by NIOSH, and some methods that are different, but are expected to protect HCPs. These respirators are expected to provide protection to workers. Those with equivalent or similar protection to NIOSH-approved respirators may be available to provide respiratory protection to workers exposed to harmful airborne particulate matter. These devices are expected to be suitable alternatives to provide protection during the COVID-19 response when supplies are short. The country, conformity assessment standards, acceptable product classifications, standards and guidance documents, and protection factor determination are provided in alphabetical order. All of these respirators have protection factors of at least 10 in the countries listed below, as outlined in the standards and guidance documents specified.”

Source: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html

See next slide for approved respirators.

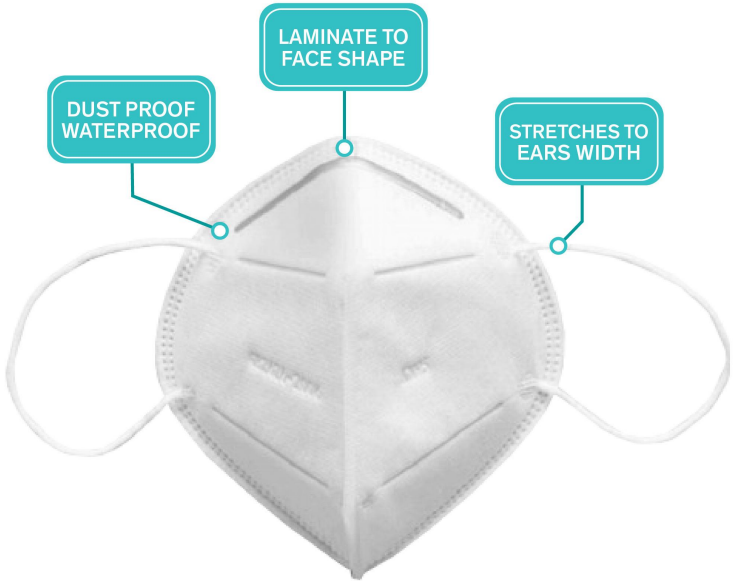
Country	Performance Standard	Acceptable product classifications	Standards/Guidance Documents	Protection Factor ≥ 10
Australia	AS/NZS 1716:2012	P3 P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PFF3 PFF2	Fundacentro CDU 614.894	YES
China	**GB 2626-2006**	**KN 100 KP100** **KN95 KP95**	**GB/T 18664--2002**	**YES**
Europe	EN 149-2001	FFP3 FFP2	EN 529:2005	YES
Japan	JMHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
Korea	KMOEL-2017-64	Special 1st	KOSHA GUIDE H-82-2015	YES
Mexico	NOM-116-2009	N100, P100, R100 N99, P99, R99 N95, P95, R95	NOM-116	YES
US NIOSH Requirements	**NIOSH approved 42 CFR 84**	**N100, P100, R100** **N99, P99, R99** **N95, P95, R95**	**OSHA 29CFR1910.134**	**YES**

Source: Center for Disease and Control (CDC)

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS (Japan JMHLW-Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO_2 clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.

SEAMLESS JOINT SAFETY

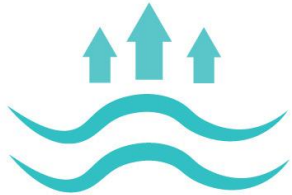


MELTBLOWN CLOTH MASK

HIGH EFFICIENCY FILTRATION

COMFORTABLE LAMINATING

HEALTHY BREATHING

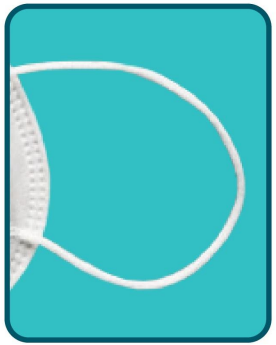


FOUR LAYERS OF PROTECTION

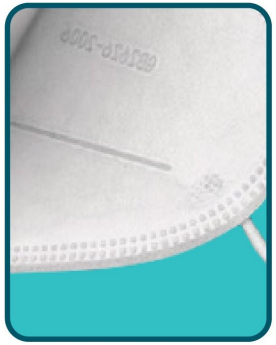
EXCELLENCE IS IN THE DETAILS

3D CUTTING

HIGH ELASTIC RUBBER BANDS

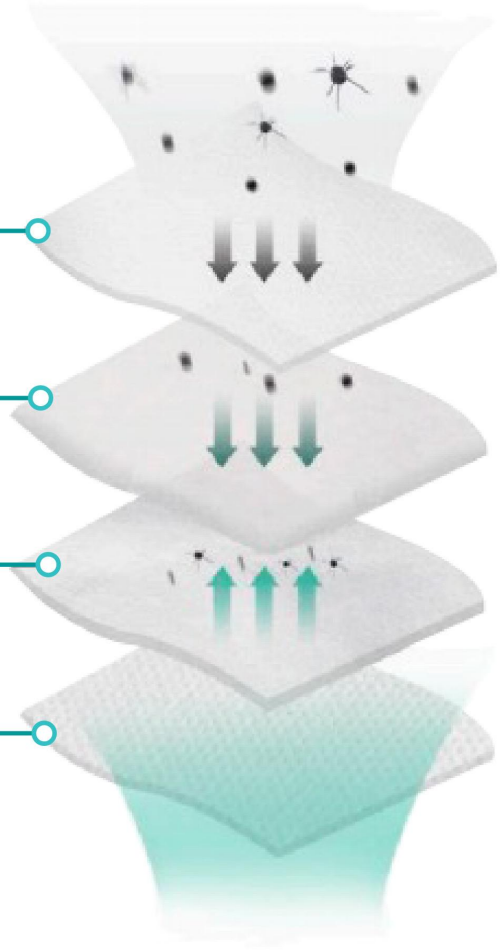


SEAMLESS PRESSURE SIDE



4 LAYERS OF PROTECTION

1. SPUN-BONDED NON-WOVEN
2. HOT AIR FILTERED COTTON
3. CORE MELT-BLOWN CLOTH
4. CLOSE SKIN NON-WOVEN



Ordering Details

Minimum Order Quantity: 100,000

Manufacturing Capability: 1,000,000 per day

Payment Terms: 50% (down payment), 25% (upon shipment), 25% (upon U.S. arrival).

Packaging: Individually packed.

Country of Production: China

Shipment Country: China or United States (depending on order volume and inventory)

FDA Approval: Proof included with each shipment.

Lead Time: 7-14 Days

All manufacturers are vetted to ensure quality and certifications.

Unredacted documents will be provided upon order initiation.

FDA Registered

Unredacted Document Available Upon Order.

CERTIFICATION OF REGISTRATION
2020

This certifies that:

[redacted]

Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807, by F&W (Shanghai) Certification Co., Ltd.

Owner/Operator Number: [redacted]
Device Listing#: See annex
Expiration Date: December. 31, 2020

2020F&W 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. F&W 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. F&W 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. F&W is not affiliated with the U.S. Food and Drug Administration.

for and on behalf of
F&W (Shanghai) Certification Co., Ltd.

exective director

Dated: March 16, 2020

F&W (Shanghai) Certification Co., Ltd. TEL: 021-62050771 E-MAIL:sales@xz-lab.com
Website: www.xz-lab.com Add: 301-302, No. 2, Lane 1515, Yunping Road, Jiading District, Shanghai, China

CERTIFICATION OF REGISTRATION
2020

Annex to Device Listing#

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
SELF SUCTION FILTER RESPIRATOR KN95, Headband folding type (K1-K100), Ear hook folding type (K1-K100)	*KHA*	*1*	[redacted]	*Repackager/Relabeler Contract Manufacturer Manufacturer Remanufacturer Foreign Private Label Distributor Foreign Exporter*

END OFTHE ANNEX

for and on behalf of
F&W (Shanghai) Certification Co., Ltd.

exective director

Dated: March 16, 2020

F&W (Shanghai) Certification Co., Ltd. TEL: 021-62050771 E-MAIL:sales@xz-lab.com
Website: www.xz-lab.com Add: 301-302, No. 2, Lane 1515, Yunping Road, Jiading District, Shanghai, China

FDA Registered

Unredacted Document Available Upon Order.

FDA

The 3rd Party Certificate of
FDA Medical Device Registration

Note:

This file is Not being issued by FDA, but SFT, as the 3rd party, produce it, intended to facilitate customer display & transmit info... following contents, FDA registered Facility/Owner/Operator&FDA listing Medical Device, are excerpted from database at www.fda.gov.

Establishment:

[redacted]Sucheng Economic and Development Zone Suqian
Jiangsu, CN 223800
Registration Number / FEI Number*:
* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set
Status: **Active**
Date of Registration Status: **2020**

Owner/Operator

[redacted]and Development Zone Suqian
Jiangsu, CN 223800
Owner/Operator Number: [redacted]

Official Correspondent

Contact Name: [redacted] Sales Director
[redacted]Sucheng Economic and Development Zone Suqian
Jiangsu, CN 223800
Tel: [redacted] E-mail: [redacted]

U.S. Agent

Contact Name: [redacted]
Address: [redacted],Katy, Texas 77449 U.S.A
Phone: [redacted] E-mail: [redacted]

Devices Listing Information

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Face Mask	LYU	1	D37****	Manufacturer

⚠ Please careful protect your Listing Number.

Approved by: Reilly

Professional FDA Registration Services, by Shanghai Shifu Testing Service Co., Ltd.
More details on the website: http://www.sft-lab.com.
Need help? Contact us, SFT, at +86(021) 51300821&sales@sft-lab.com.cn
FDA CERTIFICATE NUM: SFT20FEB006C

CE Compliant

Unredacted Document Available Upon Order.

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

Certificate of Compliance

No. [redacted]

Technical Construction File no. QW-0231-231-211EN

Certificate's Holder: [redacted]
Guangzhou, Guangdong, China

Certification ECM Mark: ®

Product: Disposable protective mask
Model(s): Ear hook plane type(K1-K100)

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. 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: 23 March 2020

Expiry date: 22 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

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

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

Certificate of Compliance

No. [redacted]

Technical Construction File no. II-423-431-2313EN1

Certificate's Holder: [redacted]
Guangzhou, Guangdong, China

Certification ECM Mark: ®

Product: Self-suction filter protective mask
Model(s): Headband folding type(K1-k100)
Ear hook folding type(K1-K100)

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.

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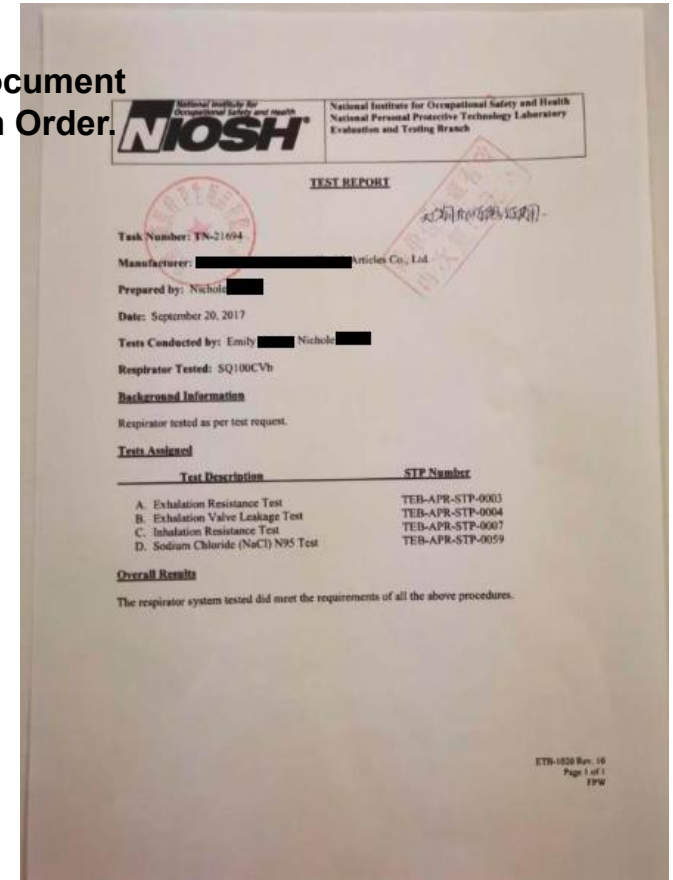
N95 FFP2 Face Mask

N95 FFP2 Face Mask

NIOSH Certified

Unredacted Document Available Upon Order.



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Evaluation and Testing Branch

TEST REPORT

Task Number: TN-21694

Manufacturer: [redacted] Articles Co., Ltd.

Prepared by: Nichole [redacted]

Date: September 20, 2017

Tests Conducted by: Emily [redacted] Nichole [redacted]

Respirator Tested: SQ100CVh

Background Information

Respirator tested as per test request.

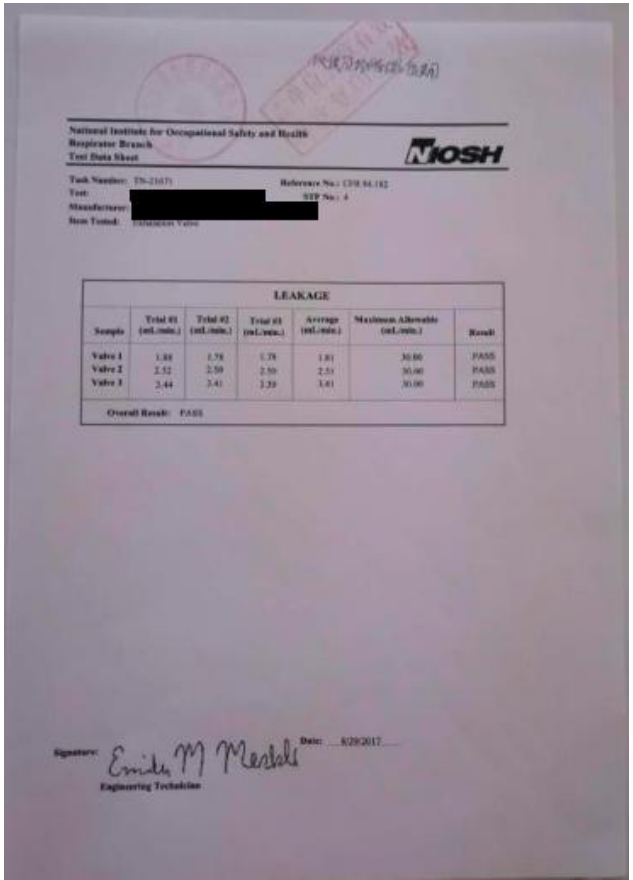
Tests Assigned

Test Description	STP Number
A. Exhalation Resistance Test	TEB-APR-STP-0003
B. Exhalation Valve Leakage Test	TEB-APR-STP-0004
C. Inhalation Resistance Test	TEB-APR-STP-0007
D. Sodium Chloride (NaCl) N95 Test	TEB-APR-STP-0059

Overall Results

The respirator system tested did meet the requirements of all the above procedures.

ETB-1020 Rev. 10
Page 1 of 1
FPW



National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-21671 Reference No.: CFR 84.182
Test: STP No.: 4
Manufacturer: [redacted]
Item Tested: Exhalation Valve

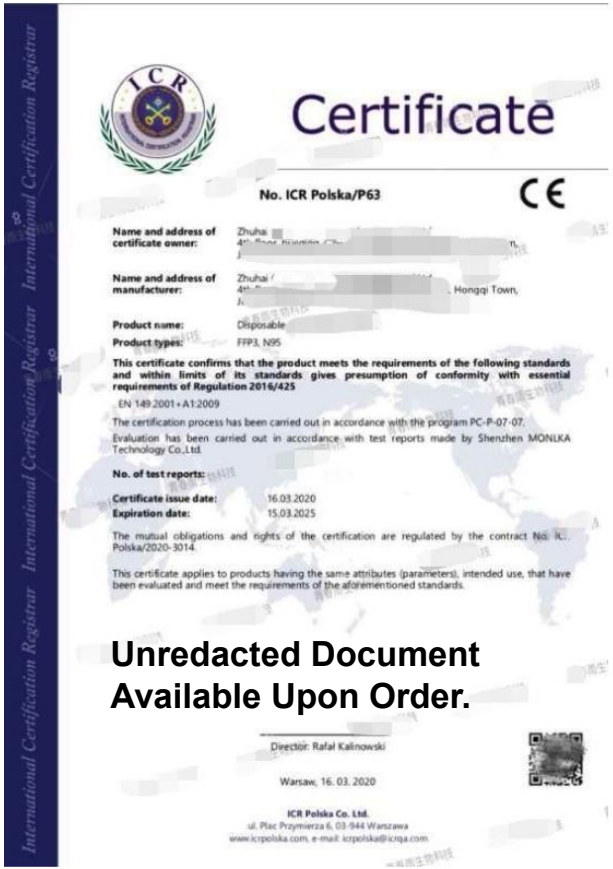
LEAKAGE

Sample	Trial #1 (mL/min.)	Trial #2 (mL/min.)	Trial #3 (mL/min.)	Average (mL/min.)	Maximum Allowable (mL/min.)	Result
Valve 1	1.88	1.78	1.78	1.81	30.00	PASS
Valve 2	2.52	2.50	2.50	2.51	30.00	PASS
Valve 3	3.44	3.41	3.39	3.41	30.00	PASS

Overall Result: PASS

Signature: Emily M Mesick Date: 8/29/2017
Engineering Technician

N95 FFP3 (CE & FDA Certified)



Certificate

No. ICR Polska/P63

CE

Name and address of certificate owner: Zhuhai [redacted]

Name and address of manufacturer: Zhuhai [redacted] Hongqi Town, [redacted]

Product name: Disposable

Product types: FFP3, N95

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test reports made by Shenzhen MONLKA Technology Co.,Ltd.

No. of test reports:

Certificate issue date: 16.03.2020

Expiration date: 15.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3014.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

Unredacted Document Available Upon Order.

Director: Rafał Kalinowski

Warsaw, 16. 03. 2020

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

International Certification Registrar International Certification Registrar International Certification Registrar

Certificate of Conformity

NO.: 10062813

This is certifies that:

Applicant : ZHUHAI [redacted]

Address : 4th floor, building 2, No.1[redacted]

Manufacturer : ZHUHAI QI[redacted]TD

Address : 4th floor [redacted] Town [redacted]NA

Device Listing : D374136 (Respirator, surgical)

EUT : Particulate respirator

Models : N95, FFP3(the product photo see the annex)

Test Standard : Food and Drug Administration Regulation

This certificate is affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, such registration having been verified as effective by Shenzhen Monlka Technology Co.,Ltd as of the date hereof, and Shenzhen Monlka Technology Co.,Ltd will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2020. Registration information can also be found on the FDA website, it can be found by enter the company name, registration number, administrator number, product model, etc. The website is

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

FDA

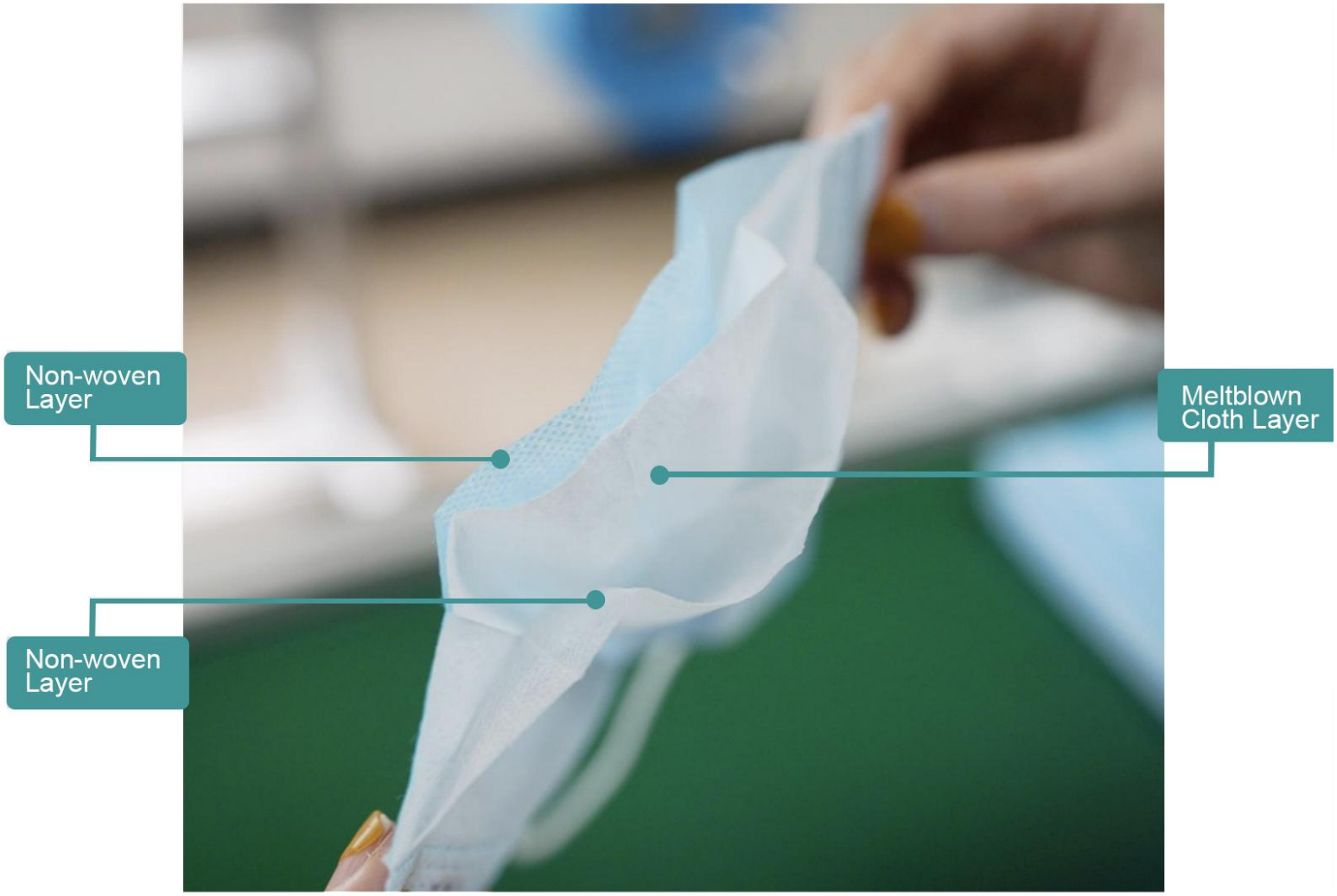
Shenzhen MONLKA Technology Co.,Ltd
Building A , B ,Baishi Science & Technology Park, Qiaoxia Road, Qiaotou Street, Baoan District, Shenzhen, Guangdong, China
www.monlka.cn Tel:0755-23569402

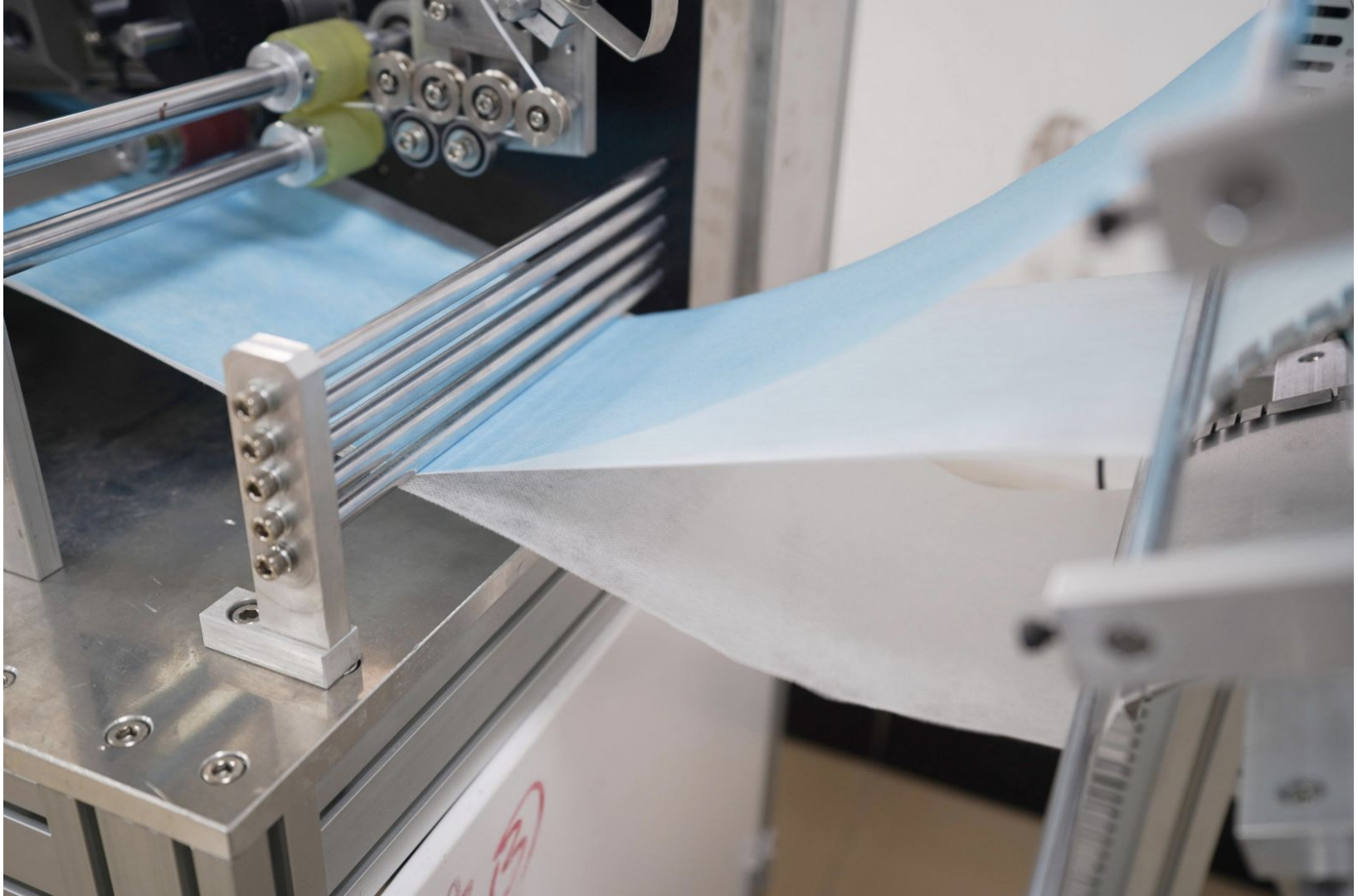
Shenzhen MONLKA Technology TESTING

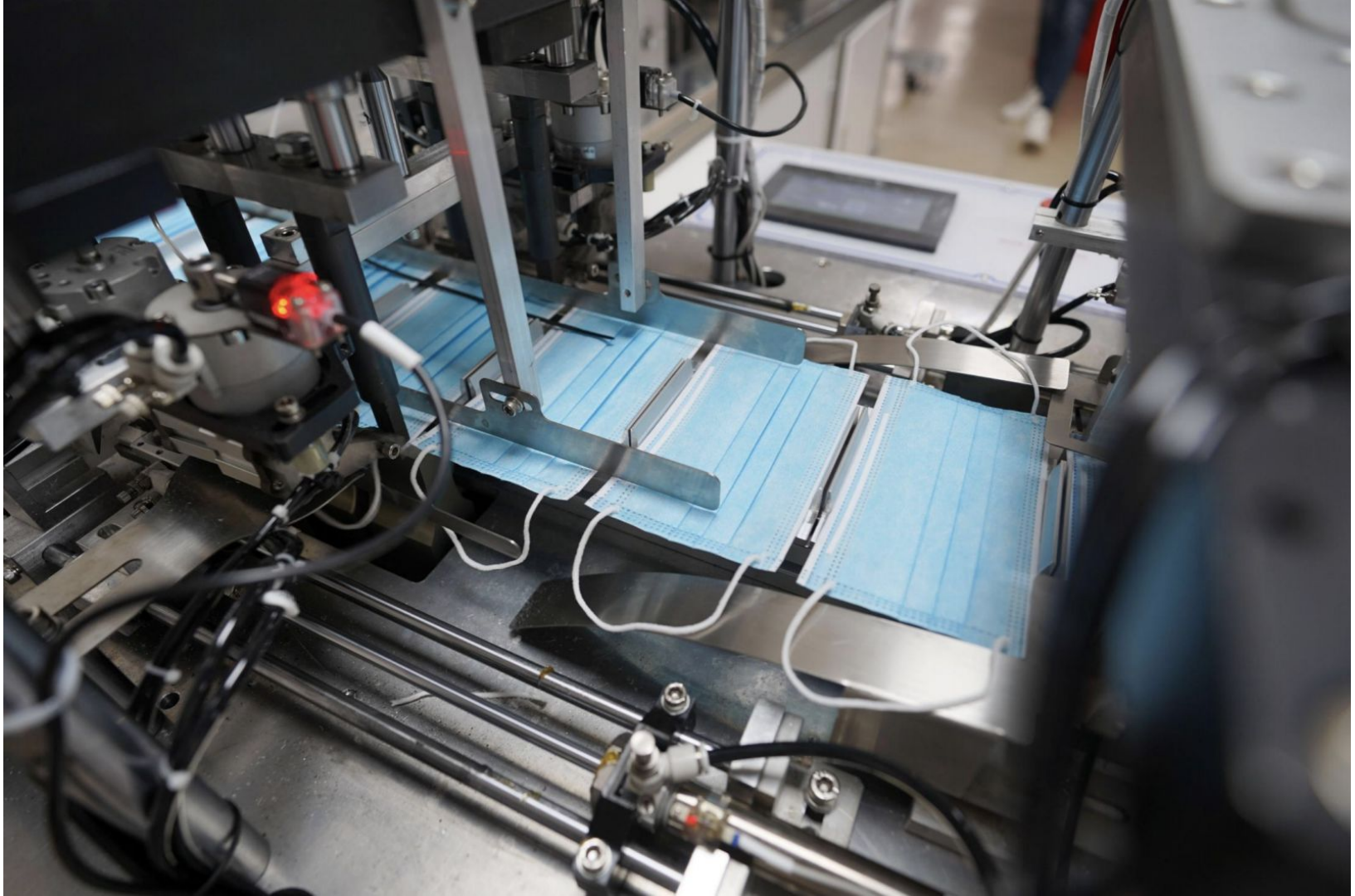
Manager

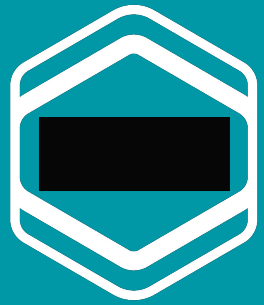
Mar. 16, 2020

3-Ply Disposable Masks


Non-woven Layer
Meltblown Cloth Layer
Non-woven Layer







MEDICAL

For more information contact Jack [redacted]

Email: jack@[redacted].com