

# MEZORISON

Web: [www.mezorrison.com.cn](http://www.mezorrison.com.cn)



# MEZORISON MZC-1895 DATA

Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd

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# ABOUT US

Mezorrison Health Science & Technology (Shenzhen) Co., Ltd (also known as MEIZHUANGCHEN Health Technology (Shenzhen) Co.,Ltd). was founded in 2013 with a registered capital of 50 million RMB. Mezorrison is a manufacturer of non-medical FFP2 masks integrating design, production and sales. The company covers an area of 12000m<sup>2</sup>, including 2200m<sup>2</sup> for production line, 8000m<sup>2</sup> for workshop and 1800m<sup>2</sup> for office and living area.

Our company mainly produces all kinds of civil protective masks, with domestic production medical grade qualification, with domestic GB2626-2019 standard, EN149:2001 + A1:2009, CE, FDA and other certification qualifications, with a daily output of 4-5 million

In line with the concept of "quality as the key, customer first", the company takes advantage of the Dongfeng of "product upgrading" and "quality products", and constantly strives to move towards high standardization, so as to better meet social needs.



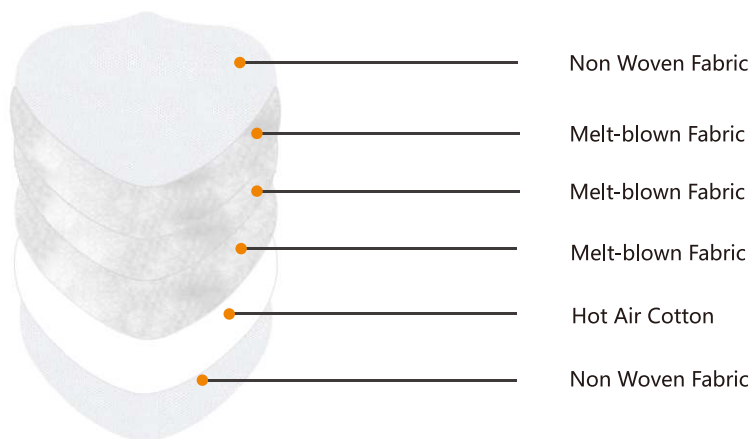
## Filtering Half Mask (Model:MZC-1895)

Open spot welding:  
Ultrasonic welding, firmly prevent ear  
strap from falling off

Built-in bridge:  
Easily adjust fit, reduce harmful inhalation

One-way air valve:  
Inhale airtight exhale open, cut off the pollution at the  
same time the effective discharge heat moisture

Widen the knitting ear strap:  
Reduce strangeness and improve comfort



### FFP3 Product Box Gauge:

1pcs/bag 20bags/box 24 boxes/carton

Box size: 150\*120\*190mm

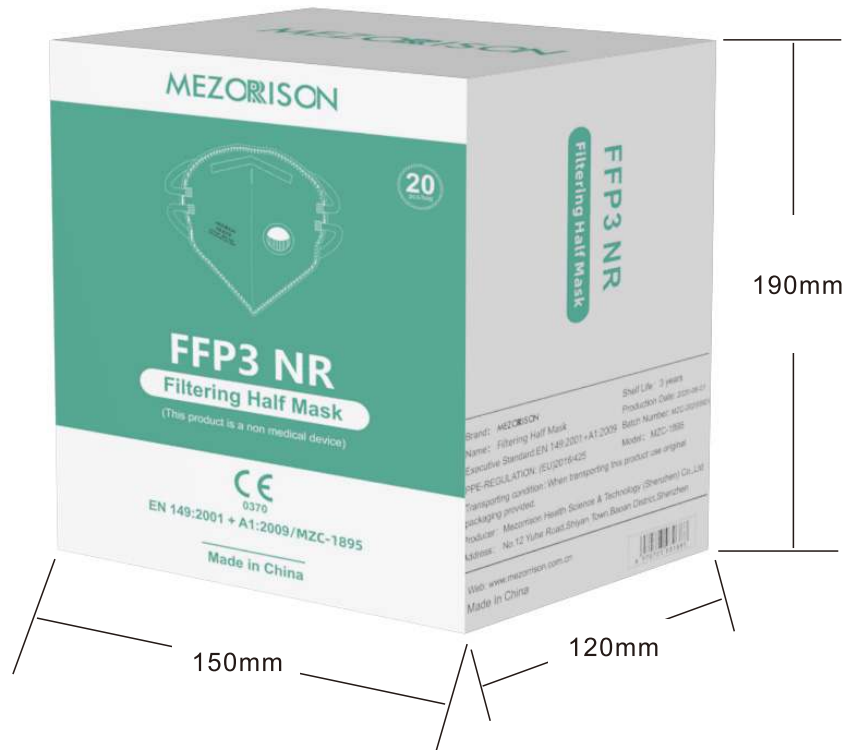
Carton size: 480\*410\*510mm

NW:7.8KG GW:9KG

## Filtering Half Mask (Model:MZC-1895)



## Filtering Half Mask (Model:MZC-1895)



Color Box Stereogram



Outer Box Stereogram



统一社会信用代码  
91440300077520338H

**营 业 执 照**  
(副 本)



名 称 美庄臣健康科技(深圳)有限公司

类 型 有限责任公司

法定代表人 陈平

成 立 日 期 2013年08月27日

住 所 深圳市宝安区石岩街道官田社区玉和山庄12号301  
(在宝安区石岩街道塘坑路8号厂房3栋二层设有经营场所从事经营活动)

**重 要 提 示**

1. 商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目,取得许可审批文件后方可开展相关经营活动。
2. 商事主体经营范围和许可审批项目等有关企业信用事项及年报信息和其他信用信息,请登录左下角的国家企业信用信息公示系统或扫描右上方的二维码查询。
3. 各类商事主体每年须于成立周年之日起两个月内,向商事登记机关提交上一自然年度的年度报告。企业应当按照《企业信息公示暂行条例》第十条的规定向社会公示企业信息。

登 记 机 关

  
2020 年 07 月 17 日

国家企业信用信息公示系统网址:<http://www.gsxt.gov.cn>

国家市场监督管理总局监制

Whitelist official website:

<http://www.cccmhpie.org.cn/kywz.aspx>

The screenshot displays the official website of the China Medical Health Products Import and Export Association (CCCMHPIE). The header includes the organization's logo, name in Chinese and English, and navigation links for English, login, and registration. A search bar is present in the top right corner.

The main content area features a search results table for companies that have obtained foreign standard certification or registration for medical materials and non-medical masks. The search criteria entered are "Meizhuangchen".

| 企业名称 (中文)         | 企业名称 (英文)                                         | 产品类别  | 统一社会信用代码           | 国外注册认证情况 |
|-------------------|---------------------------------------------------|-------|--------------------|----------|
| 美庄臣健康科技 (深圳) 有限公司 | Meizhuangchen Health Technology(Shenzhen)Co.,Ltd. | 非医用口罩 | 91440300077520338H | 欧盟CE     |

Below the search results, there is a section for "友情链接" (Friendly Links) with buttons for government departments, industry organizations, international institutions, and industry portals.

The footer contains contact information, address (Beijing), copyright notice, and a QR code linking to the association's WeChat official account.

## EUA Whitelist website:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas>

|                                                                                                 |                                                 |              |
|-------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------|
| Co., Ltd.                                                                                       |                                                 |              |
| Jiangsu Yimao Filter Media Co., Ltd                                                             | 9570K                                           | • IF         |
| Jinhua Jiadaifu Medical Supplies Co., Ltd.                                                      | Disposable Non-Medical Face Mask (KN95)         | • IF         |
| Jinwells (Tianjin) Science and Technology Co., Ltd.                                             | JWS-1, JWS-2                                    | • JV<br>• JV |
| Jinyi (Tianjin) Medical Technology Co., Ltd.                                                    | JY9501                                          |              |
| Lanshan Shendun Technology Co., Ltd.                                                            | SD-KN95                                         | • IF         |
| Liaoning Dalian Jieying Energy Saving Environmental Protection Technology Development Co., Ltd. | JY-FH-F, JY-FH                                  | • JY<br>• JY |
| Meizhuangchen Health Technology (Shenzhen) Co., Ltd.                                            | ENKN95-001                                      |              |
| ORICH Medical Equipment (Tianjin) Co., Ltd.                                                     | N95 Folded Form (Non-sterile)                   | • IF         |
| Putian Sisen Technology Co., Ltd.                                                               | AIBANA 001                                      |              |
| Qingdao Bioforce-aid Technology Co., Ltd.                                                       | G9501                                           |              |
| Qingdao Huaren Medical Product Co., Ltd.                                                        | HRKFAM, HRKFBM                                  |              |
| Qingdao Miuton Medical Co., Ltd                                                                 | Stereoscopic type ear worn KN95 Protective Mask | • IF         |
| Qingzhou Yaowang Pharmaceutical Co., Ltd                                                        | N95-FWJ                                         | • IF         |
| Raxwell Industrial Technology (Shanghai) Co., Ltd                                               | RX9501                                          | • IF         |
| Risheng Special Medical & Health Articles Co., Ltd.                                             | R171000VH-20 KN95-20 FFB3 NR, R1701000VH-20     | • IF         |



中认认证有限公司

## 质量管理体系认证证书

注册号: 27320Q20870R0S

兹证明

美庄臣健康科技(深圳)有限公司

统一社会信用代码: 91440300077520338H

注册地址: 深圳市宝安区石岩街道官田社区玉和山庄12号301

(在宝安区石岩街道塘坑路8号厂房3栋二层设有经营场所从事经营活动)

审核地址: 广东省深圳市宝安区石岩街道官田社区玉和山庄12号301

(在宝安区石岩街道塘坑路8号厂房3栋二层设有经营场所从事经营活动)

邮编: 518108

管理体系符合

GB/T19001-2016/ISO9001:2015 质量管理体系标准

该体系认证所覆盖的范围

民用口罩的生产

证书有效期内, 获证组织须每年至少接受一次监督审核, 经审核合格后, 机构更新二维码信息, 发放监督合格证。本证书可在国家认证认可监督管理委员会官方网站 ([www.cnca.gov.cn](http://www.cnca.gov.cn)) 及中认认证有限公司官方网站 ([www.zrcn.com](http://www.zrcn.com)) 查询详细信息。

初次获证日期: 2020年11月13日

签发日期: 2020年11月13日

有效期至: 2023年11月12日



中认认证有限公司

签发:

车海波

地址: 成都市青羊区蜀金路1号3栋14层1413号

电话: 400-025-9001



Zhongren Certification Co., Ltd.

## QMS CERTIFICATION OF REGISTRATION

Certification No.: 27320Q20870R0S

Awarded to

Mezorison Health Science & Technology (Shenzhen) Co., Ltd.

Unified Social Credit Code: 91440300077520338H

Registration Address: No. 12 Yuhe Road, Shiyuan Town, Baoan District, Shenzhen

Audit Address: 2nd Floor, Gaoke Building, No. 8 Tangkeng Rd, Shiyuan, Baoan District, Shenzhen, China

Post Code: 518108

The Quality Management System of the above organization has been assessed and found to be in accordance with the requirements of the standard:

GB/T19001-2016 idt ISO9001:2015

Certification Scope of the Management System

Production of civilian face masks

Validity of the certificate, certified organizations subject to supervision and review at least once a year, after the examination and approval, the organization updates the two-dimensional code information, issuance of certificates of conformity for supervision and audit. The certificate information is available at the Certification and Accreditation Regulatory Commission official website ([www.cnca.gov.cn](http://www.cnca.gov.cn)) query, but also through the company's website ([www.zrcn.com](http://www.zrcn.com)) query.

First certified date: Nov.13, 2020

Date of Issued: Nov.13, 2020

Valid date: Nov.12, 2023



Zhongren Certification Co., Ltd.

Issued by: 车海波

Address: Room 1413, Floor 14, Building 3, No. 1 Shuijin Road, Qingyang District, Chengdu

Tel: 400-025-9001

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Campus UAB – Ronda de la Font del Carme s/n  
08193 Bellaterra (Barcelona)  
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www.applus.com



## CERTIFICADO DE EXAMEN UE DE TIPO EU-TYPE EXAMINATION CERTIFICATE



No. 0370-4228-PPE/B

|                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>ORGANISMO NOTIFICADO Nº</b><br>NOTIFIED BODY NUMBER                                                                                                                                                                                      | 0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)                                                                                                                                                                                                                                                           |
| <b>SOLICITANTE</b><br>APPLICANT                                                                                                                                                                                                             | <b>Mezorison Health Science &amp; Technology (Shenzhen) Co.,Ltd.</b><br>No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen                                                                                                                                                                      |
| <b>FABRICANTE</b><br>MANUFACTURER                                                                                                                                                                                                           | <b>Mezorison Health Science &amp; Technology (Shenzhen) Co.,Ltd.</b><br>2nd floor, Gaoke building, No.8 Tangkeng Rd, Shiyan, Baoan district, Shenzhen, China                                                                                                                                        |
| <b>REGlamento de aplicación para dar la conformidad / APPLICABLE REGULATION TO GIVE CONFORMITY:</b><br><b>REGlamento (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL</b><br>REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT |                                                                                                                                                                                                                                                                                                     |
| <b>PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD</b><br>CONFORMITY ASSESSMENT PROCEDURE                                                                                                                                                     | Módulo // Module: <b>B</b><br><b>EXAMEN UE DE TIPO / EU TYPE EXAMINATION</b>                                                                                                                                                                                                                        |
| <b>IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)</b><br>IDENTIFICATION OF THE PPE (TYPE NUMBER)                                                                                                                                                   | Ref.: MZC-1895<br>Filtering Half Mask                                                                                                                                                                                                                                                               |
| <b>NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI</b><br>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE                                                                                                                  | FFP3 NR                                                                                                                                                                                                                                                                                             |
| <b>NORMAS ARMONIZADAS / HARMONISED STANDARDS</b>                                                                                                                                                                                            | EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado.<br>EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking |
| <b>FECHA DE EMISIÓN / ISSUE DATE</b>                                                                                                                                                                                                        | 20/08/2020                                                                                                                                                                                                                                                                                          |
| <b>VALIDEZ HASTA / VALIDITY UNTIL</b>                                                                                                                                                                                                       | 20/08/2025                                                                                                                                                                                                                                                                                          |

El presente certificado se mantendrá vigente durante 5 años siempre que el producto descrito no sea modificado y cumpla los requisitos esenciales de salud y seguridad establecidos en el Reglamento (UE) 2016/425. Para asegurar dicho cumplimiento, este certificado deberá ir acompañado de la documentación correspondiente a la Evaluación de Conformidad con el tipo según módulo C2, D (realizada por un Organismo Notificado, según frecuencia establecida).

This certificate will remain valid for 5 years as long as the indicated product is not modified and fulfills the essential requirements of health and safety established in (EU) Regulation 2016/425. To ensure such compliance, this certificate must be accompanied by the documentation corresponding to the Conformity Assessment to type according to C2, D (carried out by a Notified Body according, to the established frequency).

**Applus+**  
LGA Technological Center, S.A.  
Xavier Ruiz Peña  
Managing Director, Product Conformity B.U.



Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.  
This document is not valid without its technical annex, whose number coincides with the number of certificate.

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Technical Annex Ed. 1  
20/08/2020

## ANEXO TÉCNICO TECHNICAL ANNEX

0370-4228-PPE/B

### I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

|                                                                                                                            |                                                                    |
|----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| <b>MARCA</b><br>BRAND                                                                                                      | Mezorison                                                          |
| <b>IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)</b><br>IDENTIFICATION OF THE PPE (TYPE NUMBER)                                  | Ref.: MZC-1895<br>Filtering Half Mask                              |
| <b>NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI</b><br>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE | FFP3 NR                                                            |
| <b>INFORME DE ENSAYO</b><br>TEST REPORT                                                                                    | S20081201101E issued by Shenzhen NTEK Testing Technology Co., Ltd. |

**NTEK** 北测  中国认可  
国际互认  
检测  
TESTING  
CNAS L5516

Report No.: S20081201101E page 1 of 13

## Test Report

**Applicant:** Mezorison Health Science & Technology (Shenzhen) Co., Ltd.  
**Address:** No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen

**The following sample(s) was/were submitted and identified on behalf of the client as:**  
**Product name:** Filtering Half Mask  
**Model:** MZC-1895  
**Brand:** Mezorison  
**Manufacturer:** Mezorison Health Science & Technology (Shenzhen) Co., Ltd.  
**Address:** 2nd floor, Gaoke building, No.8 Tangkeng Rd, Shiyan, Baoan district, Shenzhen, China  
**Classification:** FFP3 NR  
**Sample quantity:** 127 Pcs

**Sample Received Date:** Aug. 12, 2020  
**Testing Period:** Aug. 12, 2020~ Aug. 18, 2020

**Test Requirement:**  
According to the requirement of the client, the test item(s) of the sample is according to the standard EN149:2001+A1:2009.

**Test Result(s):** Please refer to the following page(s)

**Test Method:** Please refer to the following page(s)

Compiled by:  Reviewed by:   
Approved by:  Date: 2020-08-19

Shenzhen NTEK Testing Technology Co., Ltd. | Address: 1/F, Building E, Fenda Science Park, Sanwei Community, Xixiang Street, Bao'an District, Shenzhen 518126 P.R.China. | Tel: +86-755-36995508 | Fax: +86-755-36995505 http://www.ntek.org.cn  
Complaint Tel: +86-755-36995510 | Complaint E-mail: complaint@ntek.org.cn

**NTEK** 北测 :S20081201101E page 12 of 13

**Sample photo(s):**



Fig.1



Fig.2

K Testing Technology Co., Ltd. | Address: 1/F, Building E, Fenda Science Park, Sanwei Community, Xixiang Street, Shenzhen 518126 P.R.China. | Tel: +86-755-36995508 | Fax: +86-755-36995505 http://www.ntek.org.cn  
+86-755-36995510 | Complaint E-mail: complaint@ntek.org.cn

**NTEK** 北测 :S20081201101E page 13 of 13



Fig.3

\*\*\*\*End of Report\*\*\*\*

Report is effective only with both signature and specialized stamp, the result(s) shown in this report is only for the sample(s) tested. Without written approval of NTEK, this report can't be used except in full.

K Testing Technology Co., Ltd. | Address: 1/F, Building E, Fenda Science Park, Sanwei Community, Xixiang Street, Shenzhen 518126 P.R.China. | Tel: +86-755-36995508 | Fax: +86-755-36995505 http://www.ntek.org.cn  
+86-755-36995510 | Complaint E-mail: complaint@ntek.org.cn

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## CERTIFICADO DE CONFORMIDAD CON EL TIPO CONFORMITY TO TYPE CERTIFICATE



No. 0370-4406-PPE/C2

|                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>ORGANISMO NOTIFICADO Nº</b><br><i>NOTIFIED BODY NUMBER</i>                                                                                                                                                                                                                                                                                               | 0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)                                                                                                                                                                                                                        |
| <b>SOLICITANTE</b><br><i>APPLICANT</i>                                                                                                                                                                                                                                                                                                                      | <b>Mezorison Health Science &amp; Technology (Shenzhen) Co.,Ltd.</b><br>No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen                                                                                                                                   |
| <b>FABRICANTE</b><br><i>MANUFACTURER</i>                                                                                                                                                                                                                                                                                                                    | <b>Mezorison Health Science &amp; Technology (Shenzhen) Co.,Ltd.</b><br>2nd floor, Gaoke building, No.8 Tangkeng Rd, Shiyan, Baoan district, Shenzhen, China                                                                                                     |
| <b>REGlamento DE APLICACIÓN PARA DAR LA CONFORMIDAD / APPLICABLE REGULATION TO GIVE CONFORMITY:</b><br><b>REGlamento (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL</b><br><i>REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT</i>                                                                                                          |                                                                                                                                                                                                                                                                  |
| <b>PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD CON EL TIPO</b><br><i>CONFORMITY ASSESSMENT PROCEDURE TO TYPE</i>                                                                                                                                                                                                                                          | Módulo // Module: <b>C2</b><br><b>BASADA EN EL CONTROL INTERNO DE LA PRODUCCIÓN MÁS EL CONTROL SUPERVISADO DE LOS PRODUCTOS A INTERVALOS ALEATORIOS</b><br><i>BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED CONTROL OF PRODUCTS AT ALEATORY INTERVALS</i> |
| <b>IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)</b><br><i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>                                                                                                                                                                                                                                                            | Ref.: MZC-1895<br>Filtering Half Mask                                                                                                                                                                                                                            |
| <b>NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</b>                                                                                                                                                                                                                                   | FFP3 NR                                                                                                                                                                                                                                                          |
| <b>FECHA DE EMISIÓN / ISSUE DATE</b>                                                                                                                                                                                                                                                                                                                        | 16/09/2020                                                                                                                                                                                                                                                       |
| <b>VALIDEZ HASTA / VALIDITY UNTIL:</b>                                                                                                                                                                                                                                                                                                                      | 16/09/2021                                                                                                                                                                                                                                                       |
| El presente certificado se mantendrá vigente durante 1 año siempre que no se modifiquen las condiciones establecidas en el Certificado de Examen UE de Tipo referenciado en el Anexo.<br><i>This certificate will remain in force for 1 year as long as the conditions established in the EU Type certificate referenced in the annex are not modified.</i> |                                                                                                                                                                                                                                                                  |

LGAi Technological Center, S.A.  
Xavier Ruiz Peña  
Managing Director, Product Conformity B.U.



Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.  
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Technical Annex Ed. 1  
16/09/2020

## ANEXO TÉCNICO TECHNICAL ANNEX

0370-4406-PPE/C2

### I. MODELOS INCLUIDOS EN EL CERTIFICADO

#### REFERENCES INCLUDED IN THIS CERTIFICATE

|                                                                                                                           |                                                                                                     |
|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| <b>Nº CERTIFICADO DE EXAMEN UE DE TIPO</b><br><i>NR. EU TYPE EXAMINATION CERTIFICATE</i>                                  | 0370-4228-PPE/B                                                                                     |
| <b>EMITIDO POR</b><br><i>ISSUED BY</i>                                                                                    | LGAi TECHNOLOGICAL CENTER S.A. (APPLUS)<br>(Organismo notificado nº 0370 / Notified Body nr. 0370). |
| <b>FECHA EMISIÓN</b><br><i>ISSUE DATE</i>                                                                                 | 20/08/2020                                                                                          |
| <b>VALIDEZ HASTA</b><br><i>VALIDITY UNTIL</i>                                                                             | 20/08/2025                                                                                          |
| <b>MARCA</b><br><i>BRAND</i>                                                                                              | Mezorison                                                                                           |
| <b>IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)</b><br><i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>                          | Ref.: MZC-1895<br>Filtering Half Mask                                                               |
| <b>NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</b> | FFP3 NR                                                                                             |
| <b>INFORME DE ENSAYO DE CONFORMIDAD CON EL TIPO</b><br><i>CONFORMITY TO TYPE TEST REPORT</i>                              | S20083103501E issued by Shenzhen NTEK Testing Technology Co., Ltd.                                  |

Report No.: S20083103501E page 1 of 10

**NTEK北测** **ILAC-MRA** **CNAS** 中国认可 国际互认 检测 TESTING CNAS L5516

## Test Report

**Applicant:** Mezorison Health Science & Technology (Shenzhen) Co., Ltd.  
**Address:** No.12 Yuhe Road, Shiyao Town, Baoan District, Shenzhen

**The following sample(s) was/were submitted and identified on behalf of the client as:**

**Product name:** Filtering Half Mask  
**Model:** MZC-1895  
**Brand:** Mezorison  
**Manufacturer:** Mezorison Health Science & Technology (Shenzhen) Co., Ltd.  
**Address:** 2nd floor, Gaoke building, No.8 Tangkeng Rd, Shiyao, Baoan district, Shenzhen, China  
**Classification:** FFP3 NR  
**Sample quantity:** 80Pcs  
**C2 Sampling done by**  
**APPLUS+ with ID**  
**number:** 20/32301226

**Sample Received** Aug. 31, 2020  
**Date:**  
**Testing Period:** Aug. 31, 2020~ Sep. 06, 2020

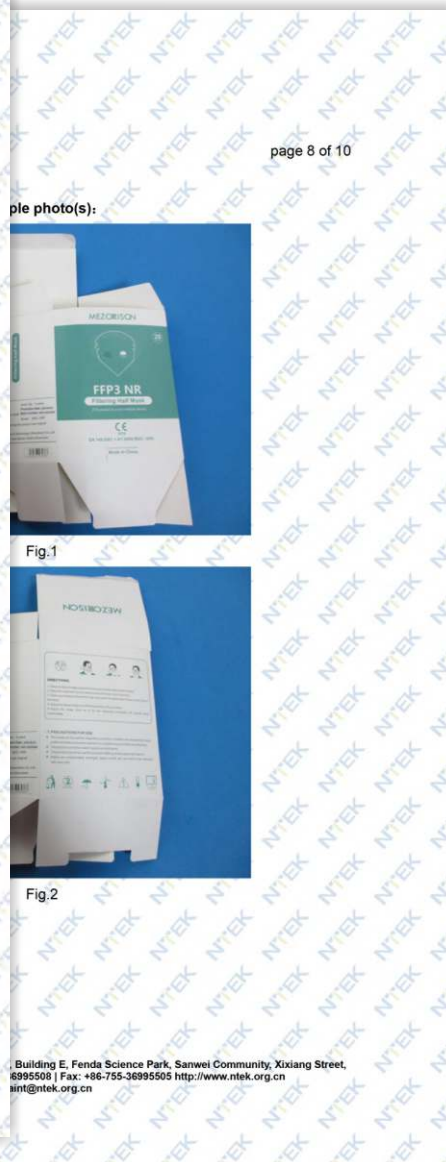
**Test Requirement:**  
 According to the requirement of the Module C2 (SPC CE-062\_EN M3 PPE) of Applus+, the test item(s) of the sample is according to the standard EN149:2001+A1:2009.

**Test Result(s):** Please refer to the following page(s)

**Test Method:** Please refer to the following page(s)

Compiled by:  Reviewed by:   
 Approved by:  Date: 2020-09-08

Shenzhen NTEK Testing Technology Co., Ltd. | Address: 1/F, Building E, Fenda Science Park, Sanwei Community, Xixiang Street, Bao'an District, Shenzhen 518126 P.R.China. | Tel: +86-755-36995508 | Fax: +86-755-36995505 http://www.ntek.org.cn  
 Complaint Tel: +86-755-36995510 | Complaint E-mail: complaint@ntek.org.cn



## CE0370 butterfly type with valve - declaration of conformity

**EU DECLARATION OF CONFORMITY**

**1. Personal protective equipment:** Filtering Half Mask (MZC-1895; FFP3 NR).

**2. Name and address of the manufacturer:**  
**Name:** Mezorison Health Science & Technology (Shenzhen) Co.,Ltd.  
**Address :** No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen

**3.This declaration of conformity is issued under the sole responsibility of the manufacturer:** Mezorison Health Science & Technology (Shenzhen) Co.,Ltd.

**4.Object of the declaration is:** Filtering Half Mask (MZC-1895; FFP3 NR).for respiratory protection against particles.

**5.The object of the declaration described in point 4 is in conformity with the relevant Union Harmonization legislation:** REGULATION (EU) 2016/425 on personal protective equipment and repealing Council Directive 89/686/EEC.

**6. Filtering Half Mask (MZC-1895; FFP3 NR). meets the FFP3 NR requirements of the harmonized standard EN 149:2001+A1:2009 used in order to confirm the conformity with the relevant Union harmonization legislation:** REGULATION (EU)2016/425 on personal protective equipment and repealing Council Directive 89/686/EEC.

**7.The notified body:** NB 0370- LGAI TECHNOLOGICAL CENTER (APPLUS).

**8. Issued by notified body:** NB 0370 - LGAI TECHNOLOGICAL CENTER (APPLUS), with address: Campus UAB, Ronda de la Font del Carme s/n, E-08193 Bellaterra (Barcelona), Spain

**9. Certification Module:** EU TYPE EXAMINATION (Module B) + INTERNAL PRODUCTIONCONTROL PLUS SUPERVISED CONTROL OF PRODUCTS AT ALLEATORY INTERVALS (Module C2)

**Signed for and on behalf of:** Mezorison Health Science & Technology (Shenzhen) Co.,Ltd.  
No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen

**Place and date of issue:** Shenzhen,

(Signature & Stamp)



## CERTIFICATION OF REGISTRATION

This certifies that:

**Mezorrisson Health Science & Technology (Shenzhen) Co., Ltd**  
No.12 Yuhe Road, Shiyan Town, Bao'an District, Shenzhen, Guangdong, 518000,  
CHINA

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

**Owner/Operator Number :** 10064314

**Listing Number:** D378809

**Product Code :** MSH

**Product :** Respirator filter

**Model(s) :** MZC-KZ-06

**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-holder'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 / Zaccheo Lee

Issued: Mar. 25, 2020

Validity Period: 2020-12-31



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

## NOTICE OF COMPLETION

To:

**Mezorrisson Health Science & Technology (Shenzhen) Co., Ltd**  
No.12 Yuhe Road, Shiyan Town, Bao'an District, Shenzhen, Guangdong, 518000,  
CHINA

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

**Owner/Operator Number :** 10064314

**Listing Number:** D413377

**Product Code :** NZJ

**Product :** Filtering Half Mask

**Model(s) :** ENKN95-001, MZC-KZ, MZC-1863, MZC-1895, MZC-2723

**Date Of Registration Status:** 2020

Agency company 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. Agency company 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 (FDA). Agency company 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 (FDA) does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Agency company is not affiliated with the U.S. Food and Drug Administration (FDA)

*Zaccheo Lee*

Chief Engineer / Zaccheo Lee

Issued: July 25, 2020

Validity Period: 2020-12-31

Establishment Registration & Device Listing Website :

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

## The second type of medical device business record certificate



### 第二类医疗器械经营备案凭证

备案编号：粤深食药监械经营备 20208235 号

|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 企业名称  | 美庄臣健康科技（深圳）有限公司                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 法定代表人 | 陈平                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 企业负责人 | 陈平                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 经营方式  | 批零兼营                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 住 所   | 深圳市宝安区石岩街道官田社区羊台山侧玉和山庄 12 号                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 经营场所  | 深圳市宝安区石岩街道官田社区羊台山侧玉和山庄 12 号                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 库房地址  | 深圳市宝安区石岩街道官田社区羊台山侧玉和山庄 12 号                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 经营范围  | 2002 年分类目录（二类）：6801，6802，6803，6804，6805，6806，6807，6808，6809，6810，6812，6813，6815，6816，6820，6821，6822，6823，6824，6825，6826，6827，6828，6830，6831，6832，6833，6834，6840（体外诊断试剂除外），6840（诊断试剂需低温冷藏运输贮存），6840（诊断试剂不需低温冷藏运输贮存），6841，6845，6846，6854，6855，6856，6857，6858，6863，6864，6865，6866，6870，6877，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外<br>2017 年分类目录（二类）：01，02，03，04，05，06，07，08，09，10，11，12，13，14，15，16，17，18，19，20，21，22，6840 体外诊断试剂，6840 体外诊断试剂（不需低温冷藏运输贮存），以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外 |

备案部门（公章）

备案日期：2020 年 02 月 27 日



## Medical device network sales record information

医疗器械网络销售信息公示

Page 1 of 1

医疗器械网络销售信息公示

关闭

## 企业信息

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |           |                                                                                                                                              |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------|
| 企业名称                 | 美庄臣健康科技（深圳）有限公司                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 社会信用代码    | 91440300077520338H                                                                                                                           |
| 法定代表人                | 陈平                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 企业负责人     | 陈平                                                                                                                                           |
| 住所                   | 深圳市宝安区石岩街道官田社区羊台山侧玉和山庄12号                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 经营场所或生产场所 | 深圳市宝安区石岩街道官田社区羊台山侧玉和山庄12号                                                                                                                    |
| 库房地址                 | 深圳市宝安区石岩街道官田社区羊台山侧玉和山庄12号                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 备案编号      | 粤深械网备202002272813                                                                                                                            |
| 医疗器械生产（经营）许可证或备案凭证编号 | 粤深食药监械经营备20208235号                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 主体业态（可多选） | <input type="checkbox"/> 医疗器械生产 <input type="checkbox"/> 医疗器械批发 <input type="checkbox"/> 医疗器械零售 <input checked="" type="checkbox"/> 医疗器械批零兼营 |
| *经营范围                | 2002年分类目录（二类）：6801，6802，6803，6804，6805，6806，6807，6808，6809，6810，6812，6813，6815，6816，6820，6821，6822，6823，6824，6825，6826，6827，6828，6830，6831，6832，6833，6834，6840（体外诊断试剂除外），6840（诊断试剂需低温冷藏运输贮存），6840（诊断试剂不需低温冷藏运输贮存），6841，6845，6846，6854，6855，6856，6857，6858，6863，6864，6865，6866，6870，6877，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外[br]2017年分类目录（二类）：01，02，03，04，05，06，07，08，09，10，11，12，13，14，15，16，17，18，19，20，21，22，6840体外诊断试剂，6840体外诊断试剂（不需低温冷藏运输贮存），以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外 |           |                                                                                                                                              |
| 联系人姓名                | 陈平                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 联系人电话     | 15989336018                                                                                                                                  |

## 销售类型

|                   |                                                                      |                        |                                                                            |
|-------------------|----------------------------------------------------------------------|------------------------|----------------------------------------------------------------------------|
| 医疗器械网络销售类型        | <input type="checkbox"/> 自建类 <input checked="" type="checkbox"/> 入驻类 | 申请日期：                  | 2020-02-27                                                                 |
| 网站名称              |                                                                      | 网络客户端应用程序名             |                                                                            |
| 网站域名              |                                                                      | 网站IP地址                 |                                                                            |
| 电信业务经营许可证编号       |                                                                      | 非经营性互联网信息服务备案编号        |                                                                            |
| 服务器存放地址           |                                                                      | 互联网药品信息服务资格证书编号（自建类必填） |                                                                            |
| 医疗器械网络交易服务第三方平台名称 | 北京京东叁佰陆拾度电子商务有限公司<br>杭州阿里巴巴广告有限公司<br>浙江淘宝网络有限公司                      | 医疗器械网络交易服务第三方平台备案凭证编号  | （京）网械平台备字【2018】第00003号<br>（浙）网械平台备字【2018】第00001号<br>（浙）网械平台备字【2018】第00004号 |
| 变更信息              |                                                                      |                        |                                                                            |

[https://amr.sz.gov.cn/szyj/zwgk/ylqxwlsx\\_detail.jsp?serialNumber=2020022735708&...](https://amr.sz.gov.cn/szyj/zwgk/ylqxwlsx_detail.jsp?serialNumber=2020022735708&...) 2020-02-29

QG07

中 华 人 民 共 和 国 海 关  
报 关 单 位 注 册 登 记 证 书

海关注册编码: 4403162A45  
组织机构代码: 077520338  
企 业 名 称: 美庄臣健康科技(深圳)有限公司

企 业 住 所: 深圳市宝安区石岩街道官田社区羊台山侧玉和山庄 12 号

企业经营类别: 进出口货物收发货人  
注册登记日期: 2017 年 4 月 13 日  
法定代表人: 陈平  
有 效 期: 长期

注册海关: 深关现场  
核发日期: 2017 年 4 月 13 日

重 要 提 示

报 关 单 位 应 当 在 每 年 6 月 30 日 前 向 海 关  
提 交 《 报 关 单 位 注 册 信 息 年 度 报 告 》, 不  
再 另 行 通 知。

中 华 人 民 共 和 国 海 关 总 署 监 制

Certificate Of Registration Of Customs Broker

**对外贸易经营者备案登记表**

备案登记编号: 03092743 进出口企业代码: 91440300077520338H

|          |                                                           |         |                    |
|----------|-----------------------------------------------------------|---------|--------------------|
| 经营者中文名称  | 美庄臣健康科技(深圳)有限公司                                           |         |                    |
| 经营者英文名称  | Mezorison Health Science & Technology (Shenzhen) Co., Ltd |         |                    |
| 组织机构代码   | 91440300077520338H                                        | 经营者类型   | 有限责任公司             |
| 住 所      | 深圳市宝安区石岩街道官田社区羊台山侧玉和山庄12号                                 |         |                    |
| 经营场所(中文) | 深圳市宝安区石岩街道官田社区羊台山侧玉和山庄12号                                 |         |                    |
| 经营场所(英文) | No. 12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen   |         |                    |
| 联系电话     | 075583818833                                              | 联系传真    | 075583866550       |
| 邮政编码     | 518000                                                    | 电子邮箱    | mezorison@126.CO M |
| 工商登记注册日期 | 2013-8-27                                                 | 工商登记注册号 |                    |

依法办理工商登记的企业还须填写以下内容

|           |            |       |                   |
|-----------|------------|-------|-------------------|
| 企业法定代表人姓名 | 陈平         | 有效证件号 | 4416119790612471X |
| 注册资金      | 5000.00 万元 | (折美元) |                   |

依法办理工商登记的外国(地区)企业或个体工商户(独资经营者)还须填写以下内容

|                    |  |       |  |
|--------------------|--|-------|--|
| 企业法定代表人/个体工商户负责人姓名 |  | 有效证件号 |  |
| 企业资产/个人财产          |  | (折美元) |  |

备注

填表前请认真阅读背面的条款,并由企业法定代表人或个体工商户负责人签字、盖章。

2017 年 4 月 24 日

备案登记机关

Record registration Form for foreign trade managers

**出入境检验检疫报检企业备案表**

编号: 17042416104000000665 备案类别: 自理企业 备案号码: 4700660586

|           |                           |                  |                    |
|-----------|---------------------------|------------------|--------------------|
| 企业名称      | 中文                        | 美庄臣健康科技(深圳)有限公司  |                    |
|           | 英文                        |                  |                    |
| 住 所       | 深圳市宝安区石岩街道官田社区羊台山侧玉和山庄12号 |                  |                    |
| 经营场所      |                           |                  |                    |
| 企业性质      | 私营企业                      | 企业类别             | 其他                 |
| 营业执照号     |                           | 统一社会信用代码(组织机构代码) | 91440300077520338H |
| 开户银行      |                           | 银行账号             |                    |
| 法定代表人/负责人 | 陈平                        | 有效证件号            |                    |
| 联 系 人     |                           | 联系电话             |                    |
| 传 真       |                           | 电子邮箱             |                    |

快件运营企业备案还须填写以下内容

|            |  |      |  |
|------------|--|------|--|
| 快递业务经营许可证号 |  | 经营范围 |  |
|------------|--|------|--|

报检专用章印模: (使用报检专用章的需提供。另附页)  
填表前请认真阅读背面的条款,并由企业法定代表人/负责人签字、盖章。

2017 年 4 月 24 日

备案机构(签字)

Record form of entry-exit inspection and quarantine declaration enterprise

## Notification of change (filing) of production project

2020/3/12

变更通知书

### 变更（备案）通知书

22004107157

美庄臣健康科技（深圳）有限公司：

我局已于二〇二〇年三月十二日对你企业申请的（许可经营项目）变更予以核准：对你企业的（章程修正案、许可信息、章程）予以备案，具体核准变更（备案）事项如下：

备案前章程修正案：

备案后章程修正案：

备案前许可信息：项目：建设项目环境影响审批（各区环保水务局审批）有效期：，项目：第三类医疗器械经营有效期：，项目：建设项目环境影响审批有效期：

备案后许可信息：项目：第二、三类医疗器械生产有效期：，项目：建设项目环境影响审批（各区环保水务局审批）有效期：

章程备案

变更前许可经营项目：净水器、智能家电产品的生产；二类医疗器械的销售。

变更后许可经营项目：净水器、智能家电产品的生产；二类医疗器械的销售；医用口罩、医用护目镜的生产。

税务部门重要提示：如您在税务局使用防伪税控系统开具增值税发票，因变更名称、住所，需到原税务局主管税务机关办税服务厅办理防伪税控设备变更发行。





Mezorison has 50 complete FFP2 non-medical protective mask production lines. The daily production capacity can reach 4 ~5 million. Our company has received the European CE certificate and all the production meets the GB2626-2019 and EN149:2001+A1:2009 standard. During the Wuhan outbreak, we actively responded to the call of the Party Committee and government, and provided strong material guarantee within our ability for the epidemic prevention and control of the whole country and even the whole world.





Our company is committed to attentively complete every single mask, we now have complete automatic and semi-automatic production line for FFP2 masks. From molding, earloop welding, sealing, laser printing, quality testing to packing, we can guarantee every single mask is produced under clean and dust-free environment, which meets the national and CE standards.

Production setup is in progress





We have rigorous standards on raw material selection, only superior materials can produce high-end products.



MEZORISON



Web: [www.mezorrison.com.cn](http://www.mezorrison.com.cn)

# THANK YOU FOR WATCHING

Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd