# Product Introduction

- Model：

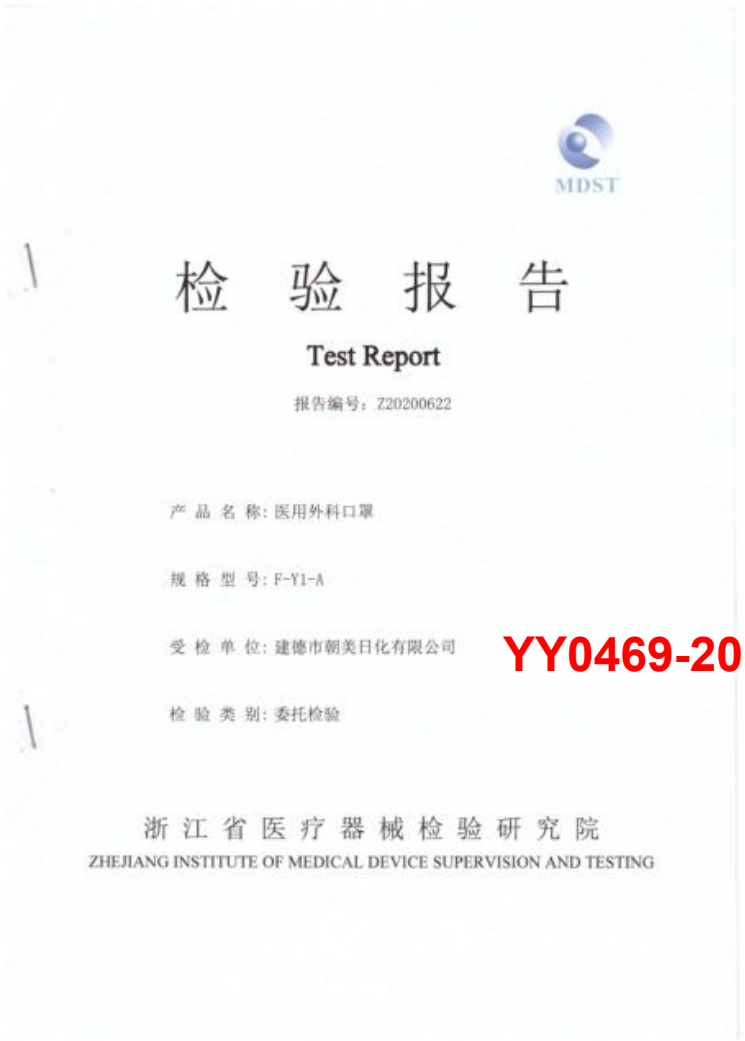
**F-Y1-A Surgical face mask**

- Style ： Flat
- Wearing style： Earloop
- Exhalation Valve ： None
- Filter Level： BFE 98
- Color blue
- Material ：

Surface layer - 25g non woven fabric

- Second layer - 20g BFE99 filter material
- Inner layer - 25g non woven fabric
- Certification ： FDA CE

# Test report



MDST

检 验 报 告

Test Report

报告编号：Z20200622

产 品 名 称：医用外科口罩

规 格 型 号：F-Y1-A

受 检 单 位：建德市朝美日化有限公司

检 验 类 别：委托检验

浙 江 省 医 疗 器 械 检 验 研 究 院

ZHEJIANG INSTITUTE OF MEDICAL DEVICE SUPERVISION AND TESTING

**YY0469-2011 China standard**

浙江省医疗器械检验研究院

检 验 报 告

报告编号：Z20200622　　共 5 页 第 1 页

| | | | |
|---|---|---|---|
| 样品名称 | 医用外科口罩 | | |
| 规格型号 | F-Y1-A | 检验类别 | 委托检验 |
| 委托人/单位 | 建德市朝美日化有限公司 | | |
| 受检单位名称 | 建德市朝美日化有限公司 | | |
| 制造单位名称 | 建德市朝美日化有限公司 | | |
| 取样方式 | 送样 | 抽样地点 | / |
| 抽样日期 | / | 抽样基数 | / |
| 抽样人 | / | 样品接受日期 | 2020-03-05 |
| 样品数量 | 50只 | 样品生产日期 | 2020.02.15 |
| 样品批号/编号 | 20200215 | | |
| 检验依据 | YY 0469-2011 | | |
| 检验项目 | 全项目（除4.9.2、4.10、4.11、4.12、4.13） | | |
| 检验日期 | 2020年03月05日~2020年03月15日 | | |
| 检验结论 | 被检样品所检项目YY 0469-2011《医用外科口罩》的要求。 | | |

批准：　职务：授权签字人　日期：2020.03.31

审核：　日期：2020.03.30

主检：　日期：2020.03.27

# Nelson Test report

Nelson Labs.
A Sotera Health company

Sponsor:
Rolen He
Jiande Chaomei Daily Chemicals Co.,Ltd.
Shangshan village Yangcunqiao town
Jiande city, Zhejiang Province, 311600
CHINA

## Latex Particle Challenge Final Report

| | |
|---|---|
| Test Article: | MEDICAL SURGICAL MASKS /Model: F-Y1-A |
| Purchase Order: | 20-243A |
| Study Number: | 1293322-S01 |
| Study Received Date: | 27 Apr 2020 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>Salt Lake City, UT 84123 U.S.A. |
| Test Procedure(s): | Standard Test Protocol (STP) Number: STP0005 Rev 07 |
| Deviation(s): | Quality Event (QE) Number(s): QE22125 |

**Summary:** This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

| | |
|---|---|
| Test Side: | Inside |
| Area Tested: | 91.5 $cm^2$ |
| Particle Size: | 0.1 µm |
| Laboratory Conditions: | 21°C, 23% relative humidity (RH) at 1042; 21°C, 23% RH at 1139 |
| Average Filtration Efficiency: | 99.67% |
| Standard Deviation: | 0.048 |

Christopher Acker electronically approved for Curtis Gerow
Study Director

10 Jun 2020 05:42 (+00:00)
Study Completion Date and Time







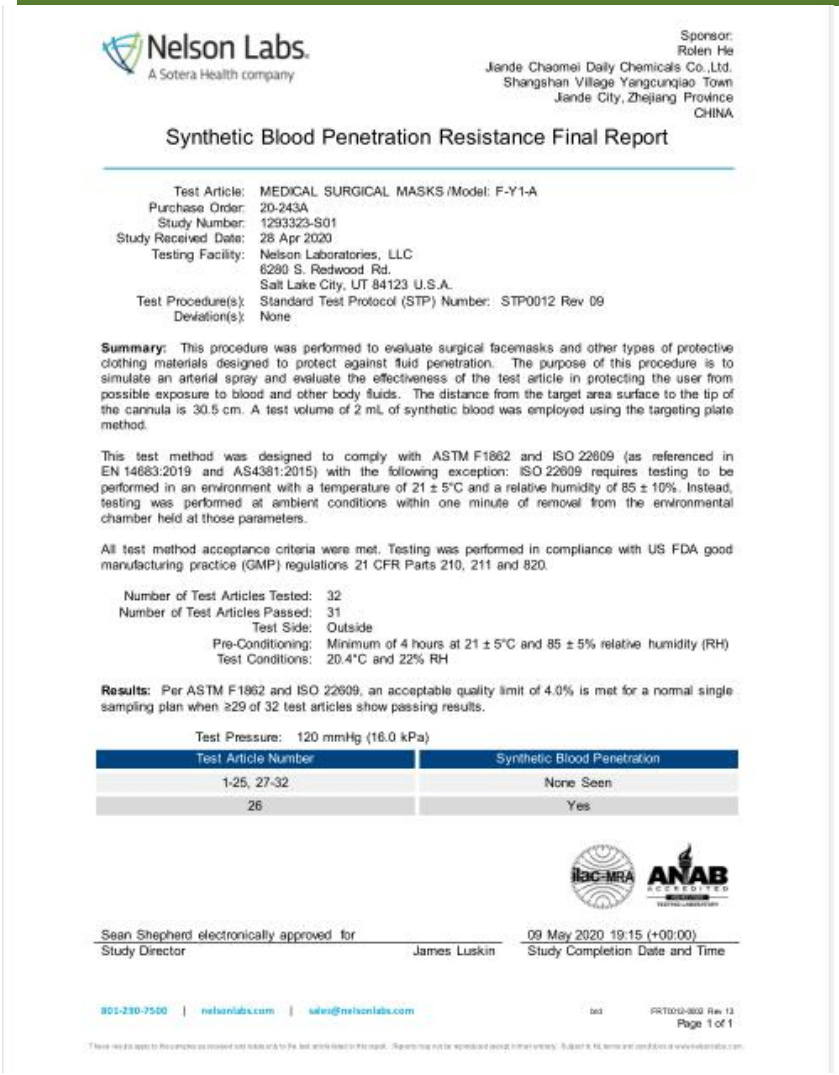
**Deviation Details:** Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

**Results:**

| Test Article Number | Test Article Counts | Average Control Counts | Filtration Efficiency (%) |
|---|---|---|---|
| 1 | 49 | 13,587 | 99.64 |
| 2 | 50 | 13,602 | 99.63 |
| 3 | 40 | 13,543 | 99.70 |
| 4 | 36 | 13,443 | 99.73 |
| 5 | 48 | 12,897 | 99.63 |

**BFE ≥ 99%**

# Nelson Test report



Nelson Labs
A Sotera Health company

Sponsor:
Rolen He
Jiande Chaomei Daily Chemicals Co.,Ltd.
Shangshan Village Yangcunqiao Town
Jiande City, Zhejiang Province
CHINA

## Synthetic Blood Penetration Resistance Final Report

Test Article: MEDICAL SURGICAL MASKS /Model: F-Y1-A
Purchase Order: 20-243A
Study Number: 1293323-S01
Study Received Date: 28 Apr 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s): None

**Summary:** This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 31
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions: 20.4°C and 22% RH

**Results:** Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

| Test Article Number | Synthetic Blood Penetration |
|---|---|
| 1-25, 27-32 | None Seen |
| 26 | Yes |

Sean Shepherd electronically approved for James Luskin
Study Director

09 May 2020 19:15 (+00:00)
Study Completion Date and Time

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

Page 1 of 1

**Level:2**

**Test Pressure:**

**120 mmHg (16.0 kPa)**

# FDA 510K & Listing

Fiscal Year 2020

**CERTIFICATION OF FDA REGISTRATION**

Cert. No.: 2020FDACERTCACH043

*This certifies that:*

**Establishment:** JIANDE CHAOMEI DAILY CHEMICALS CO., LTD
**Registered Address:** Zhangshan village Yangcunqiao town Jiande, Zhejiang, 311605, CHINA
**Registration Number:** Not Yet Assigned

*has completed the FDA Establishment Registration (as manufacturer and foreign exporter ) and Device Listing with the US Food & Drug Administration, such registration having been verified as currently effective on the date hereof by SPICA MEDTECH CORP.*

**Owner/Operator Number:** 10062722 (Device List No#: See annex )
**U.S. Agent for FDA:** SPICA MEDTECH CORP
Communications: 3265 KINNISON ST Denver,CO.80205,USA
Phone: 720 6176666 Ext. ,Email: spica_us@yahoo.com

*SPICA MEDTECH CORP 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. SPICA MEDTECH 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. Pursuant to 21 CFR 807.30, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products.*

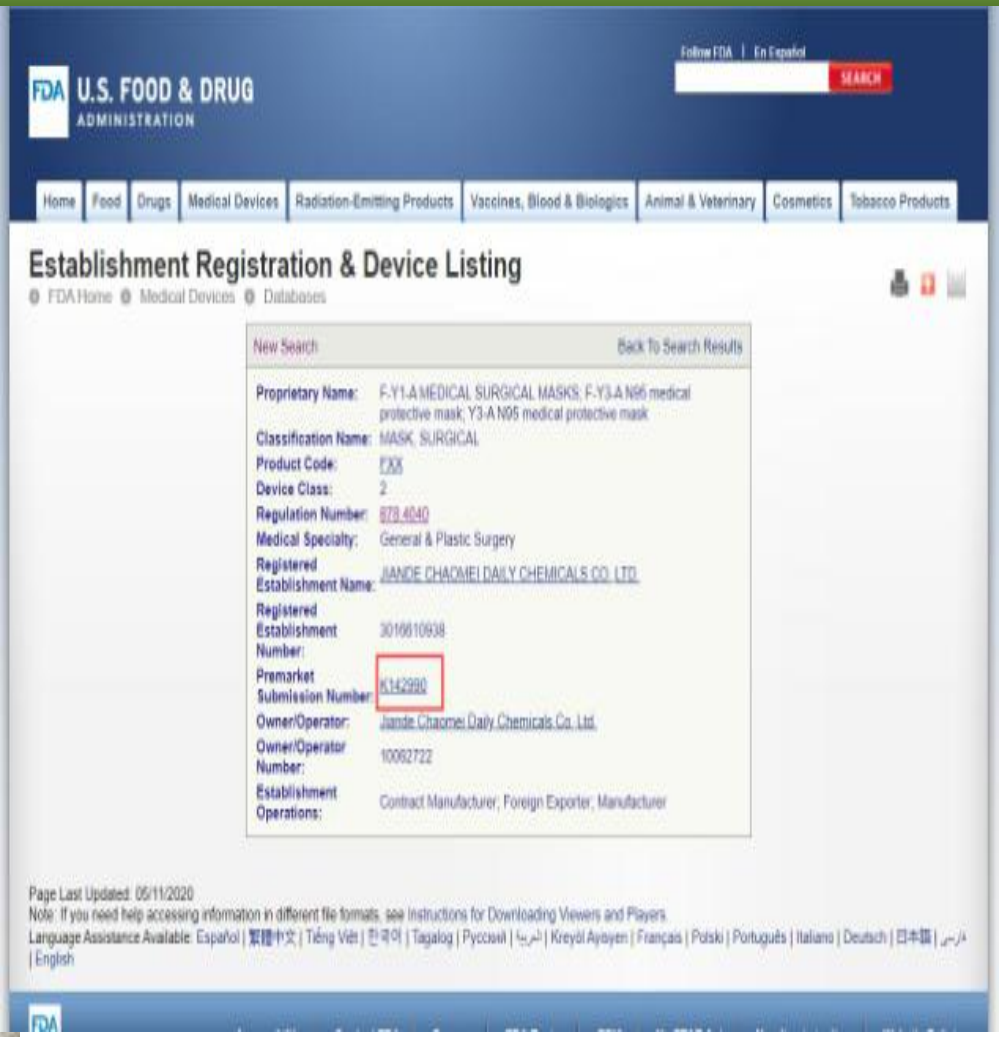
SPICA MEDTECH CORP ( In USA )
SHANGHAI SPICA MANAGEMENT CONSULTING CO.,LTD ( In China )
SPICA MEDTECH CERTIFICATION COMPANY LIMITED ( In HK )
spica_us@yahoo.com , www.spicaglobe.com

For and on behalf of
SPICA MEDTECH CORP

Authorized Signature

Spica Consulting
Regulatory Service

FDA




**D40094 K142990 FXX**

# FDA 510K & Listing

U.S. FOOD & DRUG ADMINISTRATION

## DEVICE REGISTRATION AND LISTING INFORMATION

Registration Date: May 27, 2020
Please review your registration. Registration Status: Active

| Section 01 | Type of Registration |
|---|---|
| Activities | MANUFACTURER, CONTRACT MANUFACTURER, FOREIGN EXPORTER |
| Registration Number | 3016610938 |

| Section 02 | Facility Name / Address Information |
|---|---|
| Name | JIANDE CHAOMEI DAILY CHEMICALS CO.,LTD. |
| Address | Shangshan village Yangcunqiao town, Jiande, Zhejiang, 311603, CHINA |

| Section 03 | Owner/Operator Information |
|---|---|
| Owner/Operator Number | 10062722 |
| Contact Name | Rolen He |
| Company | JIANDE CHAOMEI DAILY CHEMICALS CO.,LTD. |
| Address | Shangshan village Yangcunqiao town, Jiande, Zhejiang, 311603, CHINA |
| Phone Number | 86 - 571 - 6419000 - 3 |
| Fax Number | |
| Email Address | Rolen@cmmask.com |

| Section 04 | Official Correspondent Information |
|---|---|
| OC Contact Name | Rolen He |
| OC Business Name | JIANDE CHAOMEI DAILY CHEMICALS CO.,LTD. |
| Address | Shangshan village Yangcunqiao town, Jiande, Zhejiang, 311603, CHINA |
| Phone Number | 86 - 571 - 6419000 - 3 |
| Fax Number | |
| Email Address | Rolen@cmmask.com |

| Section 05 | Trade Names |
|---|---|

| Section 06 | United States Agent |
|---|---|
| Contact Name | SILVERDEW VEE |
| Business Name | SPICA MEDTECH CORP |
| Address | 2255 EMRSON ST<br>DENVER, COLORADO 80205<br>UNITED STATES |

**Contact Name:**
Rolen He

**Company:**
JIANDE CHAOMEI DAILY CHEMICALS CO.,LTD.

**Address:** Shangshan village Yangcunqiao town
Jiande, ZHEJIANG, 311603, CHINA

**Telephone:**
86 - 571 - 6419000 - 3

**Fax:**
-

**E-mail:** Rolen@cmmask.com

**DUNS Number:**

### United States Agent Information

**Contact Name:**
Silverdew Vee

**Contact Title:**
Mrs

**Business Name:**
SPICA MEDTECH CORP

**Address:** 2255 EMRSON ST
Denver, Colorado, 80205, UNITED STATES

**Phone:**
720 - 6176666

**Fax:**
720-6176666

**DUNS Number:**

**E-mail:** Spica_us@Yahoo.Com

### Device Listings

| Listing Number | Premarket Submission Number/Type | Product Code(s) | Device Name(s) | Activities | Importers |
|---|---|---|---|---|---|
| D373361 | Exempt | LYU | ACCESSORY, SURGICAL APPAREL | Foreign Exporter<br>Manufacturer | |
| D400094 | K142990 | FXX | Mask, surgical | Manufacturer<br>Contract Manufacturer<br>Foreign Exporter | |

https://www.accessfda.gov/drlm/drlm.htm?_flowExecutionKey=_cA80D1F40-FT00-619E-B8F4-557580F89C3F_kT9C1E885-1C4B-C1AA-6E8B-... 2/3

## 510K : K142990

| Listing Number | Proprietary Name | Confidential Flag |
|---|---|---|
| D373361 | Medical face mask | N |
| D400094 | Y3-A N95 medical protective mask | N |
| D400094 | F-Y1-A MEDICAL SURGICAL MASKS | N |
| D400094 | F-Y3-A N95 medical protective mask | N |

# Packaging

**50pcs /box  2000pcs/carton**

**Carton size: 53cm*40cm*36cm**

**Carton weight  (G.W.): 9 kgs**