

Test Report

Number: GZHT02297110

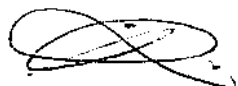
| | | | |
|-----------------------|--------------|---------------------|--------------|
| Report Ref: | GZHT02297110 | | |
| Date received: | May 29, 2020 | Date Issued: | Jun 08, 2020 |

| | |
|----------------------|--|
| Company Name: | GUANGZHOU DAYUN MEDICALTECHNOLOGY CO., LTD. BUILDING B2,NO. 632,XINTANG AVENUE, XINTANG,ZENGCHENG DISTRICT, GUANGZHOU,GUANGDONG |
| Address: | |
| Contact Name: | LIU PAN |

| | |
|---|--|
| The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As: | |
| End Uses | : Medical Face Mask |
| Ratings | : Level 1 |
| Sample Name | : Disposable Medical Mask |
| Size | : 17.5*9.5CM |
| Colour | : Blue |
| Standard | : ASTM F2100-19 ^{E1} |
| Brand | : KUNKKA |
| Manufacturer | : GUANGZHOU DAYUN MEDICAL TECHNOLOGY CO., LTD. |
| Date received/ Test Started | : May 29, 2020 |
| Ref | : DY-01 |

Test was conducted on specific items, at our client's request.

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch



Lin Lin
General Manager



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AL / abbyqzeng

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

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Test Report

Number: GZHT02297110

Original Sample Photo



Prepared And Checked By:
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General Manager

AL / abbyqzeng



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Test Report

Number: GZHT02297110

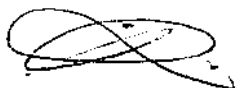
Summary of testing:

With reference to following standard:

- ASTM F2100-19^{E1} Standard Specification for Performance of Materials Used in Medical Face Masks Level 1
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods
- ASTM F2299/F2299M-17 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood
- 16 CFR Part 1610 Wearing Apparel Flammability

Materials Used in The Submitted Samples Were Found To Comply With The Requirements Of Above Standards As Specified in ASTM F2100-19^{E1} 9.1-9.5.

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch



Lin Lin
General Manager



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Test Report

Number: GZHT02297110

Tests Conducted (As Requested By The Applicant)

- 1 Wearing Apparel Flammability:
16 CFR Part 1610 (As Amendment In 2008)

| | | | |
|--|---------------|------------------------|----------------|
| X | Plain Surface | | Raised Surface |
| Burn Direction : <input checked="" type="checkbox"/> Length <input type="checkbox"/> Width | | | |
| Prelim Plain Surface : | | | |
| Length: IBE | | | |
| Width: - | | | |
| Original* (seconds) | | | |
| 1. | IBE | Requirement Class 1 | |
| 2. | IBE | | |
| 3. | DNI | | |
| 4. | DNI | | |
| 5. | DNI | | |
| 6. | - | | |
| 7. | - | | |
| 8. | - | | |
| 9. | - | | |
| 10. | - | | |
| Average : | | | |

| | | | |
|--------------------------------------|-------------------------------------|----------|---|
| Classification : | <input checked="" type="checkbox"/> | Class 1, | Normal Flammability |
| | <input type="checkbox"/> | Class 2, | Intermediate Flammability, Raised Surface |
| | <input type="checkbox"/> | Class 3, | Rapid And Intense Burning |
| Explanation Of Flammability Results: | | | |
| DNI | Did not ignite. | | |
| IBE | Ignited but extinguished. | | |

- * The disposable fabrics and garments need not to be refurbished in accordance with 16 CFR Part 1610.35 (a)(2).

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Test Report

Number: GZHT02297110

Tests Conducted (As Requested By The Applicant)

2 Bacterial Filtration Efficiency (BFE)

As Per ASTM F2100-19^{e1} Standard Specification for Performance of Materials Used in Medical Face Masks Clause 9.1 and ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.

| Test Item | Results (%) | | | | | Performance Requirement for Medical Face Mask (%) |
|---------------------------------------|--------------|--------------|--------------|--------------|--------------|---|
| | Specimen (1) | Specimen (2) | Specimen (3) | Specimen (4) | Specimen (5) | |
| Bacterial Filtration Efficiency (BFE) | >99.9 | >99.9 | 99.9 | >99.9 | 99.9 | Level 1: ≥95 |

Remarks:

1. Biological Aerosol: Staphylococcus aureus (ATCC 6538).
2. Testing side: Outside of the test specimen was facing towards the challenge aerosol.
3. Test area: 78 cm²
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls: 2300 CFU
6. The average plate count results of the negative controls: < 1 CFU
7. CFU = Colony Forming Unit

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Tests Conducted (As Requested By The Applicant)

- 3 Differential Pressure (ASTM F2100-19^{e1}, Section 9.2, Testing Refer to EN 14683:2019+AC:2019 Annex C):
Air flow: 8L/min, Test area diameter 25 mm, Test area: 4.9 cm².

| <u>Tested Sample/Component</u> | <u>Result (mm H₂O/cm²)</u> | <u>Performance Requirement for Medical Face Mask (mm H₂O/cm²)</u> Level 1: < 5.0 |
|--------------------------------|--|---|
| Specimen (1) | 4.7 | |
| Specimen (2) | 4.7 | |
| Specimen (3) | 4.3 | |
| Specimen (4) | 4.3 | |
| Specimen (5) | 4.6 | |
| Average | 4.5 | |

Remark : Test was conducted by external provider.

- 4 Resistance to Penetration by Synthetic Blood (ASTM F2100-19^{e1}, Section 9.4, Testing Refer to ASTM F1862/F1862M-17):
Synthetic blood surface tension: 0.041N/m, Distance between blow head front end and target area: 300 mm, Artificial blood volumes: 2 mL, Test Pressure: 80mmHg, Velocity: 450cm/s, Use a fixed target.

| <u>Tested Sample/Component</u> | <u>Result</u> | <u>Performance Requirement for Medical Face Mask</u> Pass Pressure at Level 1: 80 mm Hg |
|--------------------------------|---------------|--|
| Specimen (1) | None seen | |
| Specimen (2) | None seen | |
| Specimen (3) | None seen | |
| Specimen (4) | None seen | |
| Specimen (5) | None seen | |
| Specimen (6) | None seen | |
| Specimen (7) | None seen | |
| Specimen (8) | None seen | |
| Specimen (9) | None seen | |
| Specimen (10) | None seen | |
| Specimen (11) | None seen | |
| Specimen (12) | None seen | |
| Specimen (13) | None seen | |

Remark: Test was conducted by external provider

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Test Report

Number: GZHT02297110

Tests Conducted (As Requested By The Applicant)

- 5 Sub-Micron Particulate Filtration (ASTM F2100-19^{e1}, Section 9.3, Testing Refer to ASTM F2299/F2299M-17):
Particle size in aerosol: 0.1 μm , Aerosol: PSL, Test area: 100 cm^2 , Airflow: 5.33 cm/s , Sampling time: 1 min.

| <u>Tested</u> <u>Sample/Component</u> | <u>Result (%)</u> | <u>Performance</u> <u>Requirement for</u> <u>Medical Face Mask</u> <u>(%)</u> |
|--|-------------------|--|
| Specimen (1) | 98.0 | Level 1: ≥ 95 |
| Specimen (2) | 98.1 | |
| Specimen (3) | 97.4 | |
| Specimen (4) | 95.1 | |
| Specimen (5) | 95.7 | |

Remark: Test was conducted by external provider

End of Report

This report is made solely on the basis of your instructions and/or information and materials supplied by you. It is not intended to be a recommendation for any particular course of action. Intertek does not accept a duty of care or any other responsibility to any person other than the Client in respect of this report and only accepts liability to the Client insofar as is expressly contained in the terms and conditions governing Intertek's provision of services to you. Intertek makes no warranties or representations either express or implied with respect to this report save as provided for in those terms and conditions. We have aimed to conduct the Review on a diligent and careful basis and we do not accept any liability to you for any loss arising out of or in connection with this report, in contract, tort, by statute or otherwise, except in the event of our gross negligence or wilful misconduct. No copy of the test report(except for full text copy) shall be made without the written approval by Intertek.

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Latex Particle Challenge GLP Report

Test Article: Product Name: Disposable Medical Mask (Non-sterile)
Model: DY-01
Study Number: 1311779-S01
Study Received Date: 18 Jun 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: 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.

Test Side: Either Side
Area Tested: 91.5 cm²
Particle Size: 0.1 µm
Laboratory Conditions: 21°C, 31% relative humidity (RH) at 0827; 21°C, 30% RH at 0931
Average Filtration Efficiency: 99.881%
Standard Deviation: 0.0460



Alexa Sanders electronically approved
Study Director

Alexa Sanders

22 Jul 2020 20:20 (+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 | 14 | 11,908 | 99.88 |
| 2 | 16 | 12,216 | 99.87 |
| 3 | 11 | 12,914 | 99.915 |
| 4 | 26 | 13,719 | 99.81 |
| 5 | 9 | 12,514 | 99.928 |

Test Method Acceptance Criteria: Ambient background particles detected through the test system must be below 1% of the challenge total (<100 particles).

Procedures:

Test Set-up: Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2 µm rated air filter. The particle generator outlet was clamped off and the number of background particles within the test system was verified to be <100 particles at 1 cubic foot per minute (CFM). The flow rate through the test system was maintained at 1 CFM ± 5%.

An aliquot of the PSL was aerosolized using a particle generator, mixed with additional filtered air, dried and passed through the test system. The particles delivered were enumerated using a laser based particle counter.

Test Procedure: A test article was placed into the holder and the system was allowed to stabilize. The number of particles being delivered to the test article was determined (no medium in air stream) as one-minute control readings were taken prior to and after every test article. Control count averages were maintained at a level of 10,000-15,000 particles per cubic foot. One-minute counts were recorded for the test article between the control counts.

The PFE of each test article was determined by using the following equation:

$$\% PFE = \frac{C - T}{C} \times 100$$

Where: C = Combined average of the control counts
 T = Average test article counts

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

| Activity | Date |
|---|-------------|
| Study Initiation | 02 Jul 2020 |
| Phase Inspected by Quality Assurance: Latex Test | 15 Jul 2020 |
| Audit Results Reported to Study Director | 15 Jul 2020 |
| Audit Results Reported to Management | 15 Jul 2020 |

| Scientists | Title |
|-----------------|----------------|
| Denise Anderson | Supervisor |
| Alexa Sanders | Study Director |

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Nicole Widmer electronically approved
Quality Assurance

22 Jul 2020 18:46 (+00:00)
Date and Time

Synthetic Blood Penetration Resistance GLP Report

Test Article: Product Name: Disposable Medical Mask (Non-sterile)
Model: DY-01
Lot #20200601
Study Number: 1311780-S01
Study Received Date: 18 Jun 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 $21 \pm 5^{\circ}\text{C}$ and a relative humidity of $85 \pm 10\%$. 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.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 32
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at $21 \pm 5^{\circ}\text{C}$ and $85 \pm 5\%$ relative humidity (RH)
Test Conditions: 23.2°C and 21% 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 |
|---------------------|-----------------------------|
| 1-32 | None Seen |



Christopher Acker electronically approved
Study Director

Christopher Acker

22 Jul 2020 00:35 (+00:00)

Study Completion Date and Time

Test Method Acceptance Criteria: The output of synthetic blood passing through the targeting hole before and after every set of test articles must be $\leq 5\%$ (± 0.10 g) in difference from the theoretical output of 2 mL.

Procedure: A clean cannula was fixed onto the front of the valve and the reservoir was filled with synthetic blood. The reservoir pressure and timer were set to allow a differential weight of 95-102%. This was achieved by setting the valve timer to 0.5 seconds and 1.5 seconds, collecting and weighing the amount of fluid before and after the targeting hole, and then calculating the weight differences for the deliveries. After the reservoir pressure and timer duration had been adjusted, the 2 mL spray was verified by dispensing three spurts in a row through the targeting hole into a graduated cylinder and weighing. After every 16 test articles, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood.

Each test article was tested within one minute of removal from the conditioning chamber. The facemask was mounted on the test article(s) holding fixture and positioned 305 mm (12 in) from the cannula. The mask was then subjected to the 2 mL volume spray, which moved from the cannula in a horizontal path perpendicular to the facemask. This procedure used a targeting hole that blocked the initial, high-pressure portion of the synthetic blood stream and allowed only the fluid traveling at the target velocity to hit the center of the mask. Each test article was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

| Activity | Date |
|---|-------------|
| Study Initiation | 07 Jul 2020 |
| Phase Inspected by Quality Assurance: Penetration Test | 13 Jul 2020 |
| Audit Results Reported to Study Director | 14 Jul 2020 |
| Audit Results Reported to Management | 15 Jul 2020 |

| Scientists | Title |
|-------------------|----------------|
| Benjamin Sipes | Supervisor |
| Christopher Acker | Study Director |

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Eric Stembridge electronically approved
Quality Assurance

21 Jul 2020 18:19 (+00:00)
Date and Time

Bacterial Filtration Efficiency (BFE) GLP Report

Test Article: Product Name: Disposable Medical Mask (Non-sterile)
Model: DY-01
Study Number: 1311781-S01
Study Received Date: 18 Jun 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: STP0004 Rev 18
Deviation(s): None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at $1.7 - 3.0 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

All test method acceptance criteria were met.

Test Side: Inside
BFE Test Area: $\sim 40 \text{ cm}^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Test Article Dimensions: $\sim 174 \text{ mm} \times \sim 153 \text{ mm}$
Positive Control Average: 2.2×10^3 CFU
Negative Monitor Count: < 1 CFU
MPS: $2.8 \mu\text{m}$



Christopher Acker electronically approved
Study Director

Christopher Acker

11 Aug 2020 23:08 (+00:00)
Study Completion Date and Time

Results:

| Test Article Number | Percent BFE (%) |
|---------------------|--------------------|
| 1 | >99.9 ^a |
| 2 | >99.9 |
| 3 | 99.9 |
| 4 | >99.9 ^a |
| 5 | >99.9 ^a |

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to BFE.

Test Method Acceptance Criteria: The BFE positive control average shall be maintained at 1.7 – 3.0 x 10³ CFU.

The MPS control average of the challenge aerosol shall be maintained at 3.0 ± 0.3 µm.

Procedure:

BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to yield challenge level counts of 1.7 – 3.0 x 10³ CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by the bacteria laden aerosol droplets were then counted and converted to probable hit values using the positive hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of the colonies on each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

| Activity | Date |
|--|-------------|
| Study Initiation | 07 Jul 2020 |
| Phase Inspected by Quality Assurance: BFE Challenge Procedure | 14 Jul 2020 |
| Audit Results Reported to Study Director | 14 Jul 2020 |
| Audit Results Reported to Management | 15 Jul 2020 |

| Scientists | Title |
|----------------|----------------|
| Benjamin Sipes | Supervisor |
| Chris Acker | Study Director |

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Eric Stembridge electronically approved
Quality Assurance

11 Aug 2020 23:06 (+00:00)
Date and Time

Differential Pressure (Delta P) GLP Report

Test Article: Product Name: Disposable Medical Mask (Non-sterile)
Model: DY-01
Study Number: 1311782-S01
Study Received Date: 18 Jun 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: STP0004 Rev 18
Deviation(s): None

Summary: The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met.

Test Side: Inside
Delta P Flow Rate: 8 Liters per minute (L/min)
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions: ~174 mm x ~152 mm

Results:

| Test Article Number | Delta P (mm H ₂ O/cm ²) | Delta P (Pa/cm ²) |
|---------------------|--|-------------------------------|
| 1 | 5.0 | 48.7 |
| 2 | 5.0 | 49.1 |
| 3 | 5.0 | 48.9 |
| 4 | 4.7 | 46.6 |
| 5 | 4.8 | 46.9 |

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to Delta P testing.

Test Method Acceptance Criteria: The Delta P test flow rate shall be maintained at 8 L/min throughout the testing.



Sarah Guzman electronically approved
Study Director

Sarah Guzman

22 Jul 2020 14:20 (+00:00)
Study Completion Date and Time

Procedure:

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm² and Pa/cm² of test area and calculated using the following equation:

$$\text{Delta } P = \frac{\bar{M}}{A}$$

Where: \bar{M} = Average mm of water of the test replicates per test article
A = Area of the test article holder (cm²)

The test article holder used in the Delta P test has a test area of 4.9 cm².

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

| Activity | Date |
|---|-------------|
| Study Initiation | 07 Jul 2020 |
| Phase Inspected by Quality Assurance: Sample Preparation | 10 Jul 2020 |
| Audit Results Reported to Study Director | 12 Jul 2020 |
| Audit Results Reported to Management | 13 Jul 2020 |

| Scientists | Title |
|----------------|----------------|
| Sarah Smit | Supervisor |
| Sarah Guzman | Study Director |
| Benjamin Sipes | Scientist |
| Chris Acker | Scientist |

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Josilyn Stonebrook electronically approved
Quality Assurance

22 Jul 2020 14:17 (+00:00)
Date and Time

Flammability of Clothing Textiles GLP Report

Test Article: Disposable Medical Mask (Non-sterile)
Model:DY-01
Study Number: 1311783-S01
Study Received Date: 18 Jun 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: STP0073 Rev 06
Deviation(s): None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. *Step 2 - Refurbishing and testing after refurbishing*, was not performed. All test method acceptance criteria were met.

Test Article Side Tested: Outside Surface
Orientation: Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

| Class | Plain Surface Textile Fabric |
|-------|---|
| 1 | Burn time ≥ 3.5 seconds |
| 2 | Not applicable to plain surface textile fabrics |
| 3 | Burn time < 3.5 seconds |

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.



Christopher Acker electronically approved
Study Director

Christopher Acker

18 Jul 2020 00:23 (+00:00)
Study Completion Date and Time

Results:

| Replicate Number | Time of Flame Spread |
|------------------|----------------------|
| 1 | IBE |
| 2 | IBE |
| 3 | IBE |
| 4 | IBE |
| 5 | IBE |

IBE = Test Article ignited, but extinguished

Test Method Acceptance Criteria: Flame length must be approximately 16 mm (~5/8 in) from the flame tip to the opening in the gas nozzle.

Procedure: Test articles were prepared by cutting the material into approximately 50 x 150 mm swatches. Preliminary testing to establish the orientation and side of the test article to test was performed. The side and orientation that burned the fastest was used to test the test articles. Each test article was clamped into the specimen holder and placed in an oven maintained at $105 \pm 3^{\circ}\text{C}$ for 30 ± 2 minutes. The test articles were then placed in a desiccator for a minimum of 15 minutes prior to testing.

The flame length of the flammability tester was adjusted to approximately 16 mm prior to testing. Test articles were placed on the flammability rack and the stop cord was strung through the guides. The flammability timer was zeroed and testing was started. When the flame reached the stop cord, the timer stopped, and the results were recorded. Testing was terminated for test articles that did not exhibit flame spread beyond the initial application of the flame.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

| Activity | Date |
|--|-------------|
| Study Initiation | 07 Jul 2020 |
| Phase Inspected by Quality Assurance: Sample Preparation/Conditioning | 13 Jul 2020 |
| Audit Results Reported to Study Director | 14 Jul 2020 |
| Audit Results Reported to Management | 15 Jul 2020 |

| Scientists | Title |
|----------------|----------------|
| Benjamin Sipes | Supervisor |
| Chris Acker | Study Director |

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Nicole Widmer electronically approved
Quality Assurance

17 Jul 2020 18:47 (+00:00)
Date and Time



CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer Luo
Olympisch Stadion 24
1076 DE Amsterdam

Datum: 12 mei 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 29 april 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Guangzhou Dayun Medical Technology Co., Ltd. met Europees gemachtigde SUNGO Europe B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

**Disposable medical mask(Non-sterile)
(geen merknaam) (NL-CA002-2020-50865)**

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling - verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161

<http://hulpmiddelen.farmatec.nl>

Inlichtingen bij:
J.I. van de Leuv

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20201753

Bijlagen

Uw aanvraag
29 april 2020

*Correspondentie uitsluitend
richten aan het retouradres met
vermelding van de datum en het
kenmerk van deze brief.*

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

Dhr. M.J. van de Velde

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Applicant

Name: Guangzhou Dayun Medical Technology Co.,Ltd.

Address: No.632,Xintang Avenue,Xintang Town,Zengcheng Distrit
Guangzhou,Guangdong,China

EC Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable medical mask (Non-sterile)

Type: DY-01(17.5cm×9.5cm), DY-02(14.0cm×9.0cm), DY-03(12.0cm×7.0cm)

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)
Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC)
and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2013

EN ISO 10993-1:2009/AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

Signature:

Date:

2024 4 27 12

*On behalf of SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.*

Sungo
global service

[Handwritten Signature]

Authorized Signature (S)

| | | | | |
|---|--|--|----------------------|---|
| Prüfbericht-Nr.: Test Report No.: | 60382611 001 | Auftrags-Nr.: Order No.: | 168266786 | Seite 1 von 12 Page 1 of 12 |
| Kunden-Referenz-Nr.: Client Reference No.: | N/A | Auftragsdatum: Order date: | May. 28, 2020 | |
| Auftraggeber: Client: | Guangzhou Dayun Medical Technology Co., Ltd. No.632, Xintang Avenue, Xintang Town, Zengcheng District Guangzhou, Guandong, China | | | |
| Prüfgegenstand: Test item: | Disposable medical mask (Non-sterile) | | | |
| Bezeichnung / Typ-Nr.: Identification / Type No.: | DY-01 | | | |
| Auftrags-Inhalt: Order content: | Type test | | | |
| Prüfgrundlage: Test specification: | EN 14683:2019+AC:2019 except for clause 5.2.6 | | | |
| Wareneingangsdatum: Date of receipt: | May. 27, 2020 | | | |
| Prüfmuster-Nr.: Test sample No.: | 20200413 | | | |
| Prüfzeitraum: Testing period: | May. 28, 2020 to Jun. 09, 2020 | | | |
| Ort der Prüfung: Place of testing: | See page 3 | | | |
| Prüflaboratorium: Testing laboratory: | TÜV Rheinland (Shenzhen) Co., Ltd. | | | |
| Prüfergebnis*: Test result*: | Pass | | | |
| geprüft von / tested by: Jun. 15, 2020 Yazhen Xu, Amanda Liu/ Engineer | | kontrolliert von / reviewed by: Jun. 15, 2020 Angela Chen / Department Manager | | |
| Datum Date | Name / Stellung Name / Position | Unterschrift Signature | Datum Date | Name / Stellung Name / Position |
| | | | | |
| Sonstiges / Other: - The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (3 pages). - The Biocompatibility (clause 5.2.6) is not evaluated in this test report. | | | | |
| Zustand des Prüfgegenstandes bei Anlieferung: Condition of the test item at delivery: | | Prüfmuster vollständig und unbeschädigt Test item complete and undamaged | | |
| * Legende: 1 = sehr gut 2 = gut 3 = befriedigend 4 = ausreichend 5 = mangelhaft P(ass) = entspricht o.g. Prüfgrundlage(n) F(ail) = entspricht nicht o.g. Prüfgrundlage(n) N/A = nicht anwendbar N/T = nicht getestet Legend: 1 = very good 2 = good 3 = satisfactory 4 = sufficient 5 = poor P(ass) = passed a.m. test specification(s) F(ail) = failed a.m. test specification(s) N/A = not applicable N/T = not tested | | | | |
| Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. <i>This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.</i> | | | | |

| | |
|--|---|
| EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods | |
| Report Reference No. : | 60382611 001 |
| Date of issue : | See cover page |
| Total number of pages : | See cover page |
| Testing Laboratory : | TÜV Rheinland (Shenzhen) Co., Ltd. |
| Address : | 1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China |
| Applicant's name | Guangzhou Dayun Medical Technology Co.,Ltd. |
| Address : | No.632, Xintang Avenue, Xintang Town, Zengcheng District Guangzhou, Guandong, China |
| Test specification: | |
| Standard : | EN 14683:2019+AC:2019 |
| Test procedure : | Type test |
| Non-standard test method: | N/A |
| Test Report Form No. : | EN 14683:2019+AC:2019_A |
| Test Report Form Originator : | TÜV Rh (SZ) |
| Master TRF : | 2020-03 |
| Test item description : | Disposable medical mask (Non-sterile) |
| Trade Mark | KUNKKA |
| Manufacturer | Same as the applicant |
| Model/Type reference : | DY-01 |
| Classification : | Type IIR |

| List of Attachments (including a total number of pages in each attachment): | |
|--|--|
| Attachment – Photo Documentation (3 pages) | |
| Summary of testing: | |
| Tests performed (name of test and test clause): Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design | Testing location: TÜV Rheinland (Shenzhen) Co., Ltd. 1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China |
| Clause 5.2.2 Bacterial filtration efficiency (BFE) Clause 5.2.3 Breathability Clause 5.2.4 Splash resistance Clause 5.2.5 Microbial cleanliness (Bioburden) | Pony Testing International Group 2/3/4/6F., Building 35, No.680, Guiping Road, Xuhui District, Shanghai, 200233, China |

Copy of marking plate

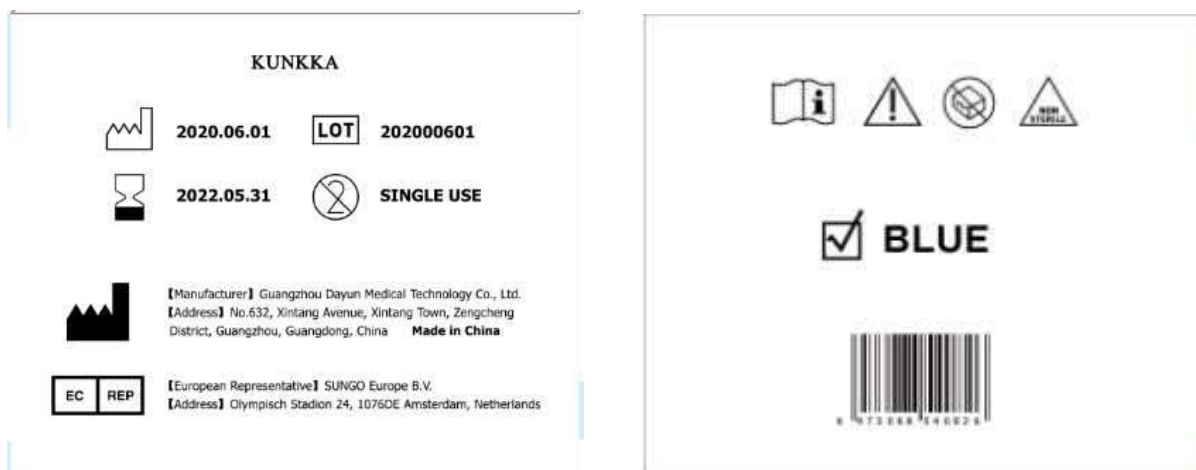
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



Shown on the front package



Shown on the front package



Shown on the side package

| | | | |
|--|--|--|--|
| <p>KUNKKA</p> <p>DISPOSABLE MEDICAL MASK</p> <p>BFE≥98% (Bacterial Filtration Efficiency)</p> <p>Model: DY-01 (17.5cmx9.5cm)</p> | <p>EN14683:2019+AC:2019 Type IIR Made in China</p> <p>Warning: This product should be stored in a cool (20°C-25°C) dry area, away from heat and direct sunlight.</p> <p>Manufacturer: Guangzhou Dayun Medical Technology Co., Ltd. (Limited) No.632, Xintang Avenue, Xintang Town, Zengcheng District, Guangzhou, Guangdong, China</p> | <p>KUNKKA</p> <p>DISPOSABLE MEDICAL MASK</p> <p>BFE≥98% (Bacterial Filtration Efficiency)</p> <p>Model: DY-01 (17.5cmx9.5cm)</p> | <p>50PCS/BOX 40BOXES/CARTON 2000PCS/CARTON</p> <p>CARTON SIZE: 51.5x46.5x34.2cm</p> |
|--|--|--|--|

Shown on the carton

| 合格证 Q.C.PASSED | |
|-------------------------|--|
| 产品名称 Product | 一次性使用医用口罩 (非灭菌) Disposable medical mask (Non-sterile) |
| 限值标准 Limit Standard | EN14683:2019+AC:2019 |
| 品 牌 Brand | KUNKKA |
| 产品型号 Model | DY-01 |
| 产品规格 Spec. | 17.5*9.5cm |
| 包装规格 Packing Spec. | 50片/盒 50pcs/box |
| 主要成分 Material | 70% 无纺布 30% 熔喷布 70% PP non-woven, 30% melt-blown filter |
| 生产批号 Lot No. | 20200601 |
| 质 检 员 QC | QC01 |
| 检验日期 Inspection Date | 2020年06月01日 1st of June, 2020 |
| 生产日期 Production Date | 2020年06月01日 1st of June, 2020 |
| 有效期限 Expiry Date | 2022年05月31日 31th of May, 2022 |
| 生产单位 Manufacturer | 广州达运医疗科技有限公司 Guangzhou Dayun Medical Technology Co., Ltd. |
| 生产地址 Address | 广州市新塘镇新塘大道632号正华工业园 No.632, Xintang Avenue, Xintang Town, Zengcheng District, Guangzhou, Guangdong, China |

Shown on the certificate

| |
|--|
| Testing Date of receipt of test item(s) : See cover page Dates of tests performed : See cover page |
| Possible test case verdicts: - test case does not apply to the test object : N/A - test object does meet the requirement : P (Pass) - test object was not evaluated for the requirement ... : N/E (collateral standards only) - test object does not meet the requirement : F (Fail) |
| General remarks: "(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report. Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator. |
| Name and address of factory (ies) : Same as the applicant |
| General product information: 1, The tested medical mask classified as type IIR. 2, The Biocompatibility (clause 5.2.6) is not evaluated in this test report. 3, The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe. |

| EN 14683:2019+AC:2019 | | | |
|-----------------------|--|---|------------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 4 | Classification | | P |
| | Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance. | Type IIR | P |
| 5 | Requirements | | P |
| 5.1 | General | | P |
| 5.1.1 | Materials and construction | | P |
| | The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. | 3 ply designed with two layers of polypropylene spunbond nonwoven and one layer of polypropylene melt-blown nonwoven. | P |
| | The medical face mask shall not disintegrate, split or tear during intended use. | | P |
| | In the selection of the filter and layer materials, attention shall be paid to cleanliness. | | P |
| 5.1.2 | Design | | P |
| | The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. | | P |
| | Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours). | With nose clip | P |
| 5.2 | Performance requirements | | P |
| 5.2.1 | General | | P |
| | All tests shall be carried out on finished products or samples cut from finished products. | | P |
| 5.2.2 | Bacterial filtration efficiency (BFE) | | P |
| | When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1. | See appended table 5.2.2 | P |
| | For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE. | Not such mask. | N/A |
| | When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. | Same characteristics and same layer-composition | N/A |
| | The lowest performing panel or area shall determine the BFE value of the complete mask | See above | N/A |

| EN 14683:2019+AC:2019 | | | |
|-----------------------|--|--|------------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 5.2.3 | Breathability | | P |
| | When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1. | See appended table 5.2.3 | P |
| | If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s). | | N/A |
| 5.2.4 | Splash resistance | | P |
| | When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1. | See appended table 5.2.4 | P |
| 5.2.5 | Microbial cleanliness (Bioburden) | | P |
| | When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1). | See appended table 5.2.5 | P |
| 5.2.6 | Biocompatibility | | N/E |
| | According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. | The biocompatibility is not evaluated in this test report. | N/E |
| | The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. | | N/E |
| | The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. | | N/E |
| | The test results shall be available upon request. | | N/E |
| 6 | Marking, labelling and packaging | | P |
| | Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. | See "Copy of marking plate". | P |
| | The following information shall be supplied: | | P |
| | a) number of this European Standard; | | P |
| | b) type of mask (as indicated in Table 1). | | P |
| | EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered. | | P |

| EN 14683:2019+AC:2019 | | | |
|-----------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 5.2.2 | | TABLE: Bacterial filtration efficiency (BFE) | | | | | | P |
|--------------------|--------------------------|--|---------------------------------|----------------------|--|---|---|---------|
| Batch/ lot no.: | Test Specimen no.: | Dimension of the test specimen L x W (mm x mm) | test area (cm ²) | Flow rate (l/min) | Mean of the total plate counts of the two positive controls | Mean plate count of the negative controls | BFE for each test specimen (%) | Remarks |
| 2020041 3 | 1 | 175×140 | 95.0 | 28.3 | 1920 | 0 | 99.90 | -- |
| | 2 | 175×140 | 95.0 | 28.3 | | | 99.90 | -- |
| | 3 | 175×140 | 95.0 | 28.3 | | | 99.90 | -- |
| | 4 | 175×140 | 95.0 | 28.3 | | | 99.90 | -- |
| | 5 | 175×140 | 95.0 | 28.3 | | | 99.90 | -- |

Supplementary information:

1, Each specimen was conditioned at 21.7 °C and 85.0 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

2, The side of the test specimen was facing towards the challenge aerosol: the inside of the test specimen.

| EN 14683:2019+AC:2019 | | | |
|-----------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 5.2.3 | | TABLE: Breathability (Differential pressure) | | | | P |
|---|--|--|---|----------------------|---------|---|
| Batch/ lot no.: | Test Specimen number- Test area number | Differential pressure for each test area (Pa/cm ²) | The averaged differential pressure for each test specimen (Pa/cm ²) | Flow rate (l/min) | Remarks | |
| 202004 13 | 1-1 | 29.9 | 29.1 | 8.0 | -- | |
| | 1-2 | 27.9 | | 8.0 | -- | |
| | 1-3 | 28.1 | | 8.0 | -- | |
| | 1-4 | 29.4 | | 8.0 | -- | |
| | 1-5 | 30.4 | | 8.0 | -- | |
| | 2-1 | 28.7 | 29.0 | 8.0 | -- | |
| | 2-2 | 28.2 | | 8.0 | -- | |
| | 2-3 | 28.7 | | 8.0 | -- | |
| | 2-4 | 30.2 | | 8.0 | -- | |
| | 2-5 | 29.3 | | 8.0 | -- | |
| | 3-1 | 29.1 | 29.2 | 8.0 | -- | |
| | 3-2 | 27.7 | | 8.0 | -- | |
| | 3-3 | 30.9 | | 8.0 | -- | |
| | 3-4 | 27.5 | | 8.0 | -- | |
| | 3-5 | 30.8 | | 8.0 | -- | |
| | 4-1 | 25.6 | 25.3 | 8.0 | -- | |
| | 4-2 | 26.1 | | 8.0 | -- | |
| | 4-3 | 25.8 | | 8.0 | -- | |
| | 4-4 | 25.2 | | 8.0 | -- | |
| | 4-5 | 23.9 | | 8.0 | -- | |
| | 5-1 | 30.2 | 30.3 | 8.0 | -- | |
| | 5-2 | 29.5 | | 8.0 | -- | |
| | 5-3 | 31.5 | | 8.0 | -- | |
| | 5-4 | 30.8 | | 8.0 | -- | |
| | 5-5 | 29.7 | | 8.0 | -- | |
| Supplementary information: | | | | | | |
| Each specimen was conditioned at <u>21.7</u> °C and <u>84.6</u> % relative humidity for <u>4</u> h to bring them into equilibrium with atmosphere prior to testing. | | | | | | |

| | | |
|-------|--------------------------|---|
| 5.2.4 | TABLE: Splash resistance | P |
|-------|--------------------------|---|

| EN 14683:2019+AC:2019 | | | | |
|-----------------------|--------------------|-----------------------------|-------------------------|---------|
| Clause | Requirement + Test | | Result - Remark | Verdict |
| Batch/ lot no.: | Test mask no.: | The material of tested mask | Test result (Pass/fail) | Remarks |
| 20200413 | 1 | See clause 5.1.1 | Pass | -- |
| | 2 | | Pass | -- |
| | 3 | | Pass | -- |
| | 4 | | Pass | -- |
| | 5 | | Pass | -- |
| | 6 | | Pass | -- |
| | 7 | | Pass | -- |
| | 8 | | Pass | -- |
| | 9 | | Pass | -- |
| | 10 | | Pass | -- |
| | 11 | | Pass | -- |
| | 12 | | Pass | -- |
| | 13 | | Pass | -- |
| | 14 | | Pass | -- |
| | 15 | | Pass | -- |
| | 16 | | Pass | -- |
| | 17 | | Pass | -- |
| | 18 | | Pass | -- |
| | 19 | | Pass | -- |
| | 20 | | Pass | -- |
| | 21 | | Pass | -- |
| | 22 | | Pass | -- |
| | 23 | | Pass | -- |
| | 24 | | Pass | -- |
| | 25 | | Pass | -- |
| | 26 | | Pass | -- |
| | 27 | | Pass | -- |
| | 28 | | Pass | -- |
| | 29 | | Pass | -- |
| | 30 | | Pass | -- |
| | 31 | | Pass | -- |
| | 32 | | Pass | -- |

| EN 14683:2019+AC:2019 | | | |
|-----------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

Supplementary information:

- 1, Each specimen was conditioned at 21.7 °C and 84.6 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
- 2, The description of target area tested: the centre of the outside of specimen.
- 3, Any technique used to enhance visual detection of synthetic blood: cotton absorbent swab.
- 4, The temperature and relative humidity for testing: 21.7 °C and 84.6 %.
- 5, Description of any pre-treatment techniques used: N/A.

| 5.2.5 | TABLE: Microbial cleanliness (Bioburden) | | | | P |
|----------------------------|--|-------------------------|---|---------|---|
| Batch/ lot no.: | Mask(under test) no.: | Weight of each mask (g) | Total bioburden per individual mask (CFU/g) | Remarks | |
| 20200413 | 1 | 3.37 | 15 | -- | |
| | 2 | 3.38 | 13 | -- | |
| | 3 | 3.38 | 6 | -- | |
| | 4 | 3.36 | 4 | -- | |
| | 5 | 3.39 | 12 | -- | |
| Supplementary information: | | | | | |

End of EN 14683 test report

Product: Disposable medical mask (Non-sterile)

Type Designation: DY-01

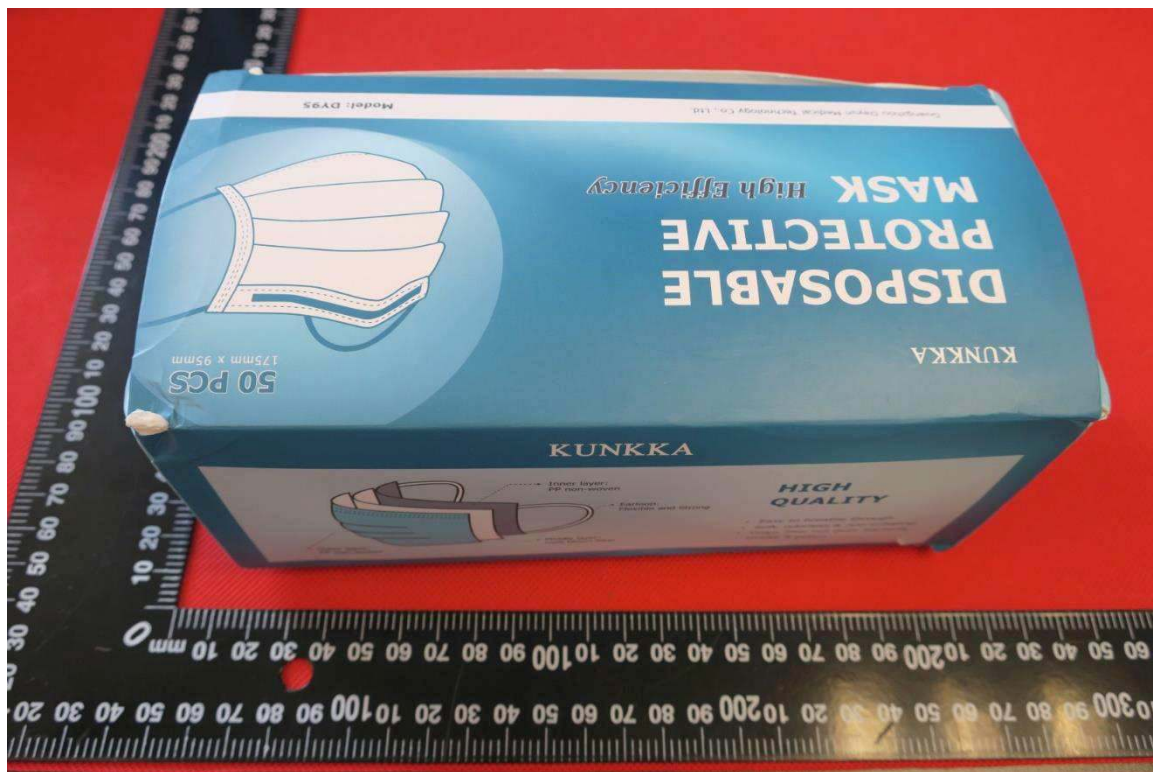


Figure 1 General view of package
(The information in this figure will be replaced by Copy of marking plate in final package)



Figure 2 General view of mask
(The information in this figure will be replaced by Copy of marking plate in final package)

Product: Disposable medical mask (Non-sterile)

Type Designation: DY-01



Figure 3 General view of mask

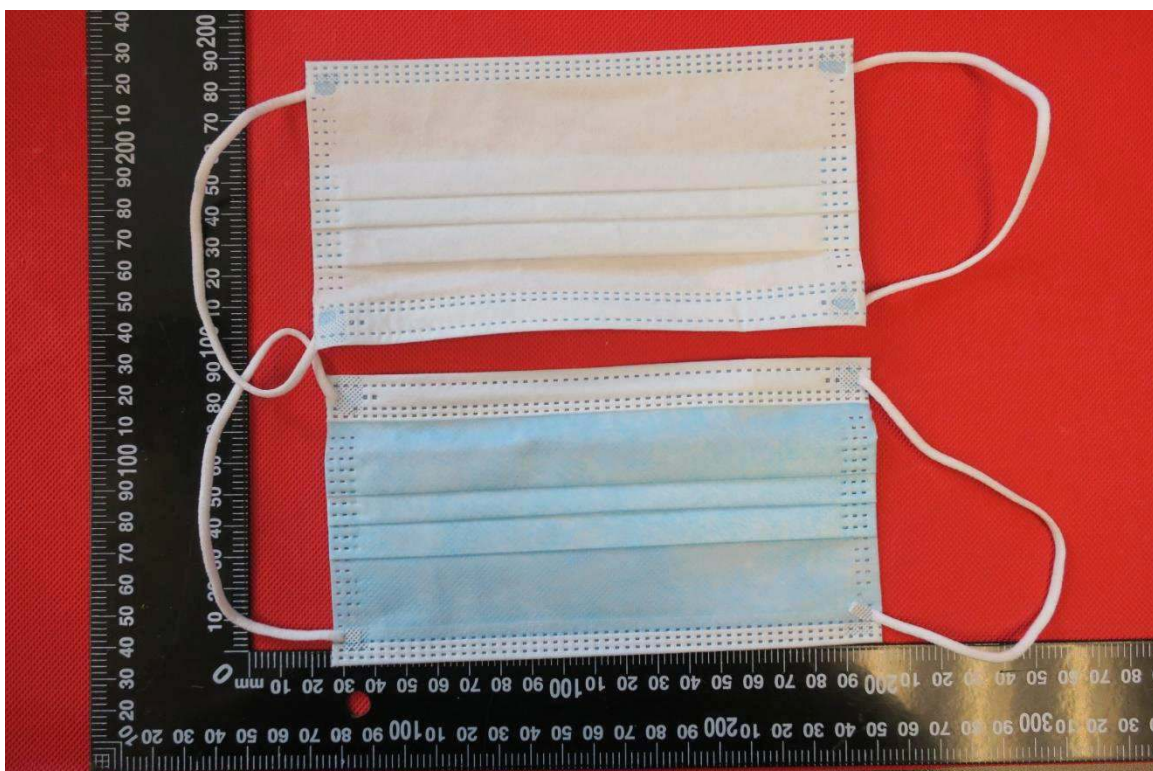


Figure 4 General view of mask

Product: Disposable medical mask (Non-sterile)

Type Designation: DY-01



Figure 5 View of mask (3 ply)

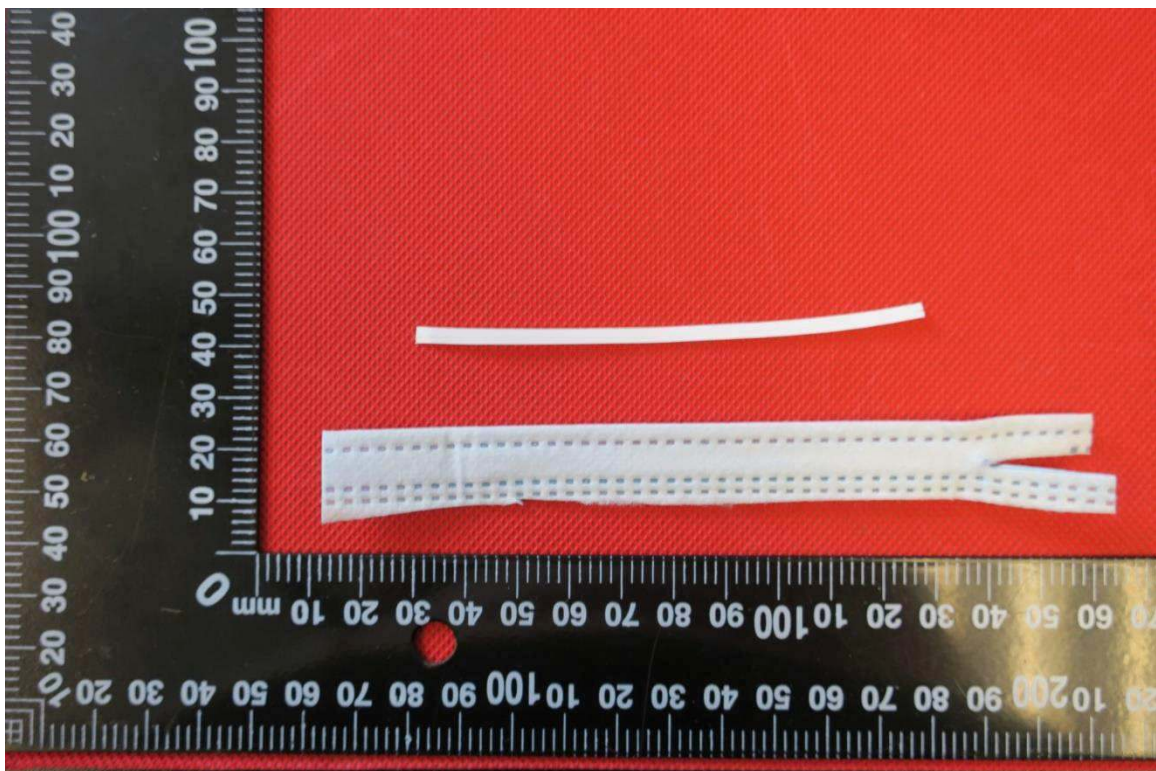


Figure 6 View of nose clip

END OF THE PHOTO DOCUMENTATION