

ATOM Health

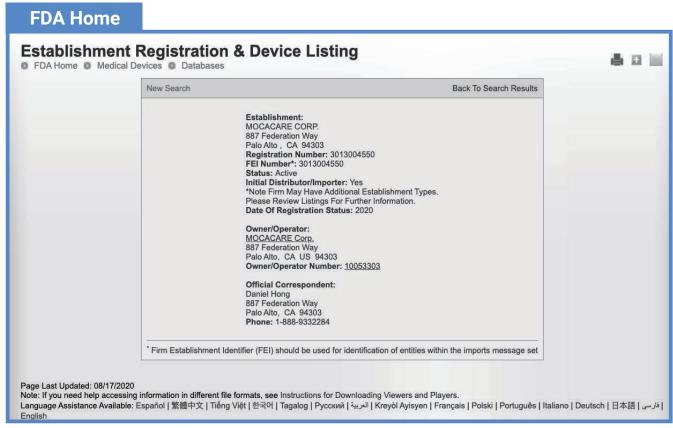
PRODUCT CATALOGUE



WE ARE ATOM HEALTH CORPORATION. WE DESIGN AND REINVENT MEDICAL DEVICES.

ATOM HEALTH CORPORATION brings multi-disciplinary team and human centered design approach to make your everyday better.

We design medical devices that are simple, convenient and thoughtful, and connect the medical device world by promoting the distribution of other innovative brands. Our innovation is supported by uncompromised quality control standards (ISO 13485, FDA, GMP, ASTM).



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EU Declaration of Conformity



EU Declaration of Conformity

Version: A

Date: June 4, 2020

Appendix I - Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description	
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC	
EN 1041:2008	Information supplied by the manufacturer of medical devices	
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes	
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices	
ANSI/AAMI PB70:2012	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)	



EU Declaration of Conformity

Version: A

Date: June 4, 2020

Declaration of Conformity

for Isolation Gown

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Isolation Gown
Legal Manufacturer:	ATOM Health Corporation 12th Floor, No.122, Songjiang Road, Taipei City, 104 Taiwan R.O.C.
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	MOCACARE isolation gown covers the torso and clothing and poses a physical barrier to the transfer of microorganisms, body fluids and particulate material. These gowns are intended to be worn once and then discarded.
MDD Classification:	Rule 1, Class I
Notified Body:	N/A
CE Certificate Reference:	N/A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Floor., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Full Quality Assurance outlined in Annex II



bsi. Test Report

bsi.



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

ATOM Health Corporation

12F.

No. 122, Songjiang Rd. Zhongshan Dist. Taipei City Taiwan

Holds Certificate Number:

MD 611326

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-05-16 Latest Revision Date: 2020-04-23 Effective Date: 2020-05-16 Expiry Date: 2023-05-15

Page: 1 of 1

bsi.

...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MKS 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

Certificate

Intertek Test Report



Test Report

ATOM HEALTH CORPORATION Date Issued : Jun 10, 2020 Applicant:

12F., No. 122, Songjiang Rd., Zhongshan Dist., Taipei City 10457,

Taiwan, R.O.C.

Sample Description:
One (1) Group of Submitted SampleS Said To Be:

**MOCACARE Isolation Gown, Blue, PE+EVA, Full Back

**AR1004 Size : 180x120cm (WxL) Lot No. : 20200604 Color : Blue Quantity : 1 Group : MOCACARE Corp.

Buyer Date Sample Received : Jun 08, 2020 : Jun 08, 2020 Date Test Started

Test Conducted:

As requested by the applicant, for details please refer to attached pages.

Authorized By:

On behalf of Intertek Testing Services

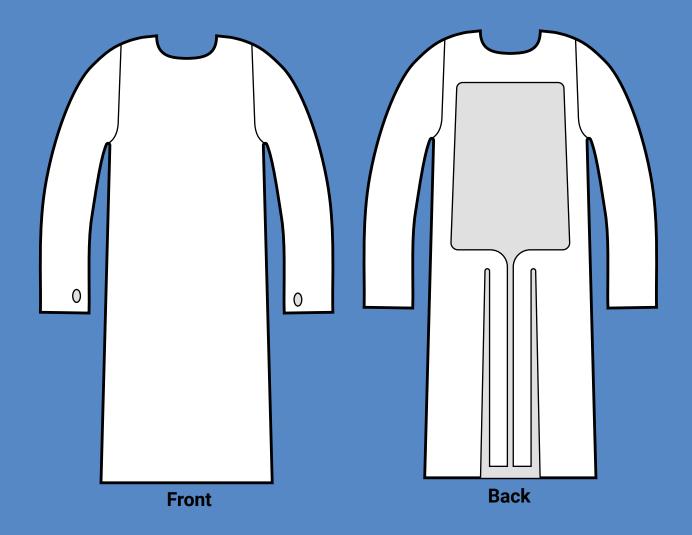
Taiwan Limited

Carol Peng General Manage Signed by: homasChou

Thomas Chou Manager

Page 1 of 3

AB1003 Isolation Gown



Material: PE and EVA

Description: Open back design, apron style neck, waist straps,

sleeves with thumb loops

Color: Blue

Size: Unisex Size,

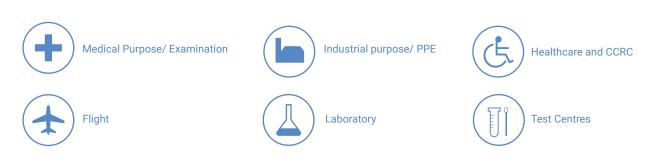
Standard: AAMI PB70 level 2

- The isolation gown is made of Polyethylene and EVA, which is lightand durable.
- Fluid resistance meets AAMI PB70 Level 2 requirement.
- Open back design, apron style neck, waist straps, sleeves with thumb loops, provide reliable protection.
- For one-time use only. Suitable for men and women of all sizes.



Applications

Can be used in hospitals, medical institutions, clinics, public transportation but not in clinical settings where AAMI PB70 Level 3 or 4 protection is warranted, etc., to provide reliable isolation and protection.

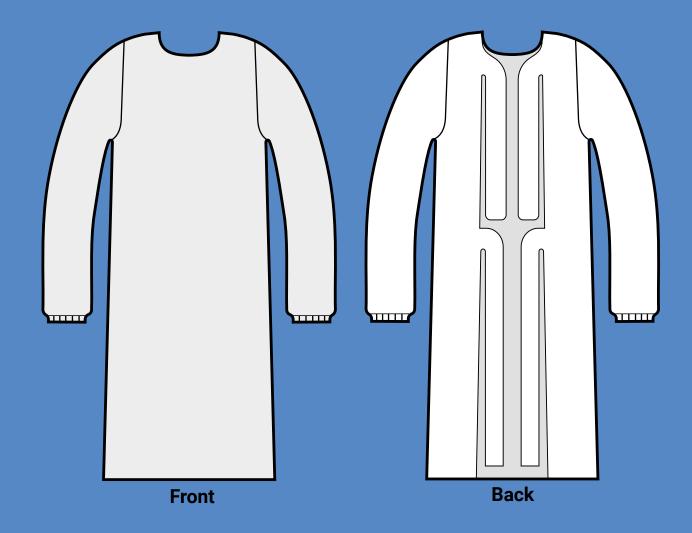


Fabric Details



Resistance to Liquid Penetration The materials has passed AATCC TM42(\leq 1.00g), AATCC TM127 (\geq 50cm).

AB1004 Isolation Gown



Material: PE and EVA

Description: Full back design, neck and waist straps, elastic cuffs.

Color: Blue

Size: Unisex Size,

Standard: AAMI PB70 level 2

- The isolation gown is made of Polyethylene and EVA, which is lightand durable.
- Fluid resistance meets AAMI PB70 Level 2 requirement.
- Open back design, apron style neck, waist straps, sleeves with thumb loops, provide reliable protection.
- For one-time use only. Suitable for men and women of all sizes.



Applications

Can be used in hospitals, medical institutions, clinics, public transportation but not in clinical settings where AAMI PB70 Level 3 or 4 protection is warranted, etc., to provide reliable isolation and protection.

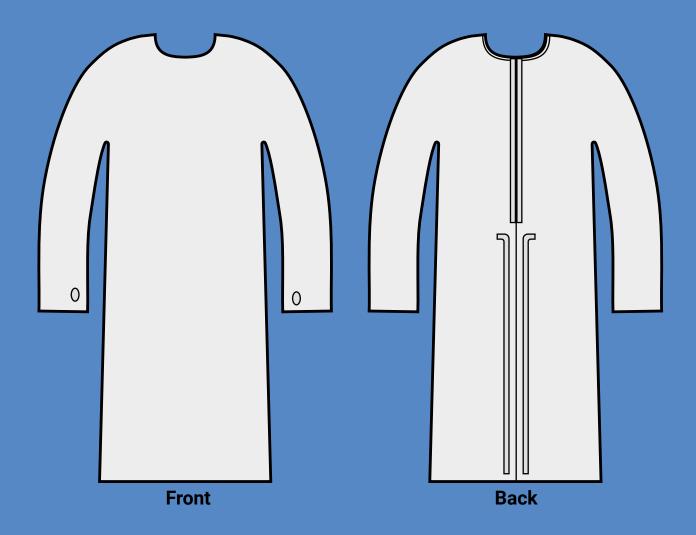


Fabric Details



Resistance to Liquid Penetration The materials has passed AATCC TM42($\leq 1.00g$), AATCC TM127 ($\geq 50cm$).

AC1007 Isolation Gown



Material: 100% polyester and highly breathable TPU

Description: Full back design, neck and waist straps, the wrist

cuff is elastic with a thumb loop

Color: White

Size: Unisex Size

Standard: This polyester and highly breathable TPU material has passed AATCC TM42

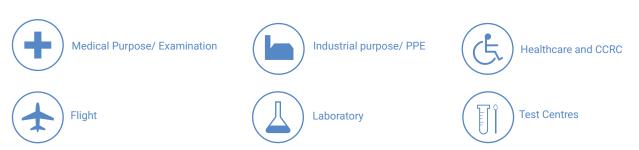
(\leq 1.00g), AATCC TM127 (\geq 50cm), ASTM F1670 and ASTM F1671M testing

- The isolation gown is made of 100% Polyester and breathable TPU, which is light and durable.
- This gown is only for low barrier protection. Do not use in a clinical setting where AAMI PB70 Level 3 or 4 protection is warranted.
- Full back design, neck and waist straps, the wrist cuff is elastic with a thumb loop, providing reliable protection.
- One-time use, suitable for men and women of all sizes.

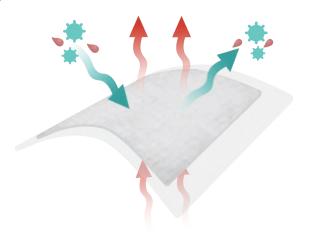


Applications

Can be used in hospitals, medical institutions, clinics, public transportation but not in clinical settings where AAMI PB70 Level 3 or 4 protection is warranted, etc., to provide reliable isolation and protection.



Fabric Details



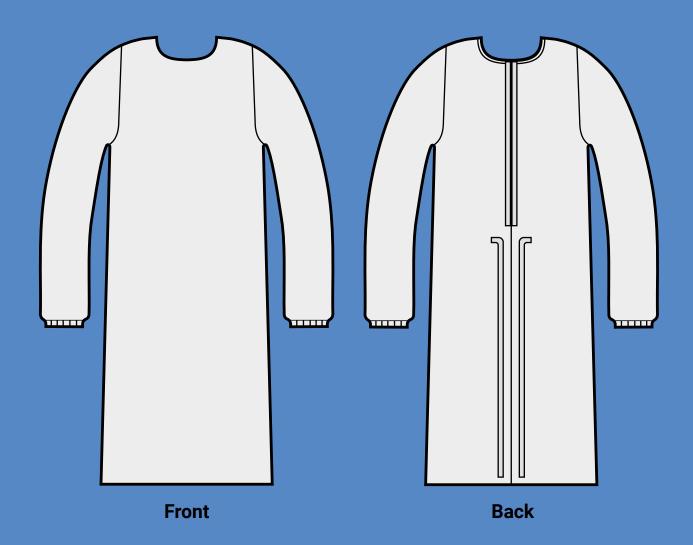
▲ Breathable Design

The isolation gowns and coverall are made of high performance moisture-permeable fabrics, so the wearer is less likely to feel stuffy when wearing the gown for a long time.

▲ Resistance to Blood and Viral Penetration

The material has ability to resist blood and viral penetration in a laboratory test, ASTM 1670 and ASTM F1671 trail system.

AD1008 Isolation Gown



Material: 4-ply SMMS fabric (40 gsm)

Description: Neck and waist straps, Élastic wrist straps, Full-back

Color: Blue

Size: Unisex Size,

Standard: AAMI PB70 level 2

- Quality 4-ply SMMS Fabric made in Taiwan: The isolation gown is made from high quality, 4-ply SMMS fabric (40 gsm) that ensures highly breathable and effective liquid barrier performance and also protection from particulate matter.
- Comfortable & Breathable 4-ply SMMS Fabric: The 4-ply SMMS fabric is more breathable and prevents temperature buildup and ideal for extended use.
- The isolation gown meets the AAMI PB70 Level 2 standard and offers reliable liquid barrier protection. The Full-back keeps patients
 and medical staff comfortable and ensures effective protection. Elastic wrist straps and thumb loops provide better fit and freedom of
 movement.

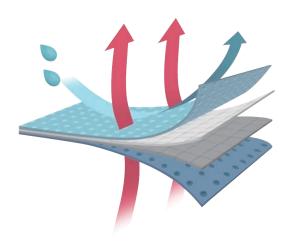


Applications

Can be used in hospitals, medical institutions, clinics, public transportation but not in clinical settings where AAMI PB70 Level 3 or 4 protection is warranted, etc., to provide reliable isolation and protection.



Fabric Details

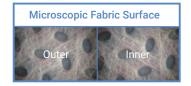


▲ Resistance to Liquid Penetration

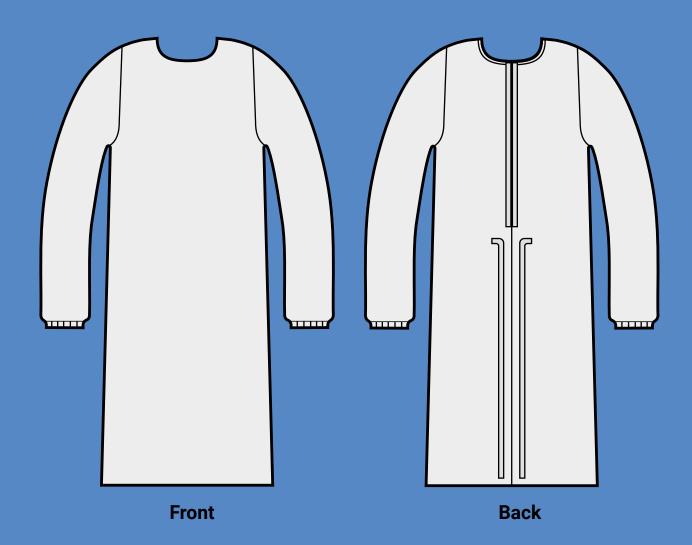
The materials has passed AATCC TM42 (\leq 1.00g), AATCC TM127(\geq 50cm).

Breathable Design

The isolation gowns and coverall are made of high performance moisture-permeable fabrics, so the wearer is less likely to feel stuffy when wearing the gown for a long time.



AD1009 Isolation Gown



Material: 4-ply SMMS fabric (50 gsm)

Description: Neck and waist straps, Élastic wrist straps, Full-back

Color: Blue

Size: Unisex Size,

Standard: AAMI PB70 level 2

- Quality 4-ply SMMS Fabric made in Taiwan: The isolation gown is made from high quality, 4-ply SMMS fabric (50 gsm) that ensures highly breathable and effective liquid barrier performance and also protection from particulate matter.
- Comfortable & Breathable 4-ply SMMS Fabric: The 4-ply SMMS fabric is more breathable and prevents temperature buildup and ideal for extended use.
- The isolation gown meets the AAMI PB70 Level 2 standard and offers reliable liquid barrier protection. The Full-back keeps patients and medical staff comfortable and ensures effective protection. Elastic wrist straps and thumb loops provide better fit and freedom of movement.

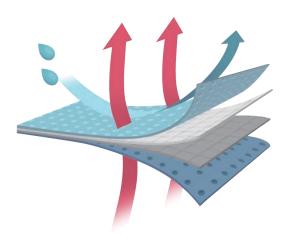


Applications

Can be used in hospitals, medical institutions, clinics, public transportation but not in clinical settings where AAMI PB70 Level 3 or 4 protection is warranted, etc., to provide reliable isolation and protection.



Fabric Details

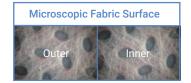


▲ Resistance to Liquid Penetration

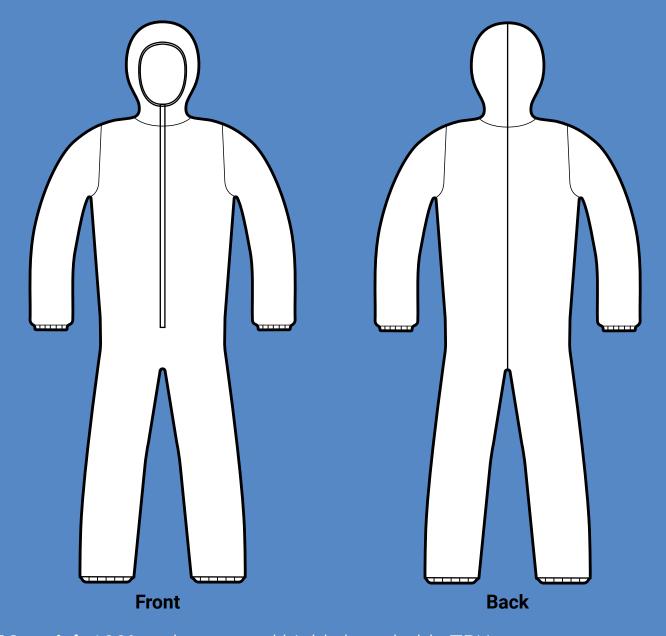
The materials has passed AATCC TM42 (\leq 1.00g), AATCC TM127(\geq 50cm).

▲ Breathable Design

The isolation gowns and coverall are made of high performance moisture-permeable fabrics, so the wearer is less likely to feel stuffy when wearing the gown for a long time.



CC1001 Coverall



Material: 100% polyester and highly breathable TPU

Description: Full pullover hood, zipper front, and elastic waist

and loop wrist and ankles

Color: White

Size: Unisex Size

Standard: This polyester and highly breathable TPU material has passed AATCC TM42 (\leq 1.00g), AATCC TM127 (\geq 50cm), ASTM F1670 and ASTM F1671M testing

- The coverall is made of 100% Polyester and highly breathable TPU, which is light and durable.
- This coverall is only for low barrier protection. Do not use in a clinical setting where AAMI PB70 Level 3 or 4 protection is warranted.
- Each piece of coverall is designed with full pullover hood, zipper front, and elastic waist and loop wrist and ankles to provide a close fit and high level of protection.
- The 100% Polyester and highly breathable TPU Coverall available individually in sizes L.









Full Pullover hood



Elastic cuffs

Applications

Can be used in hospitals, medical institutions, clinics, public transportation but not in clinical settings where AAMI PB70 Level 3 or 4 protection is warranted, etc., to provide reliable isolation and protection.



Medical Purpose/ Examination



Industrial purpose/ PPE



Healthcare and CCRC



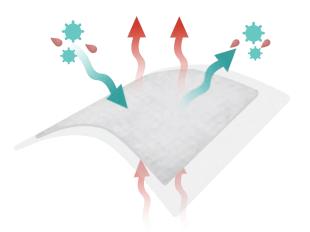


Laboratory



Test Centres

Fabric Details



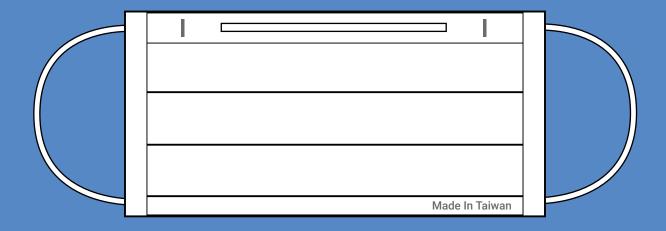
▲ Breathable Design

The isolation gowns and coverall are made of high performance moisture-permeable fabrics, so the wearer is less likely to feel stuffy when wearing the gown for a long time.

▲ Resistance to Blood and Viral Penetration

The material has ability to resist blood and viral penetration in a laboratory test, ASTM 1670 and ASTM F1671 trail system.

Medical mask



Material: Non-woven fabric, melt-blown non-woven fabric

Description: Three-layers, flat-folded mask with ear loops and a nose

piece.

Size: Unisex Size for Adult

Standard: Meet CNS14774:2018, and EN14683:2019 Type II Medical

Face Mask Standard



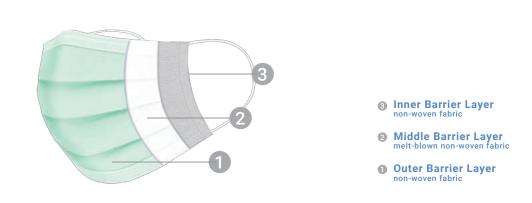
Applications

For use by general public or healthcare personal as source control only.

- Not for surgical settings, where exposure to liquid or bodily fluids are high.
- · Not for clinical settings, where infection risk level through inhalation exposure is high.
- Not to be used in the presence of a high intensity heat source or flammable gas.



Specifications



PRODUCT SPECIFICATIONS

MASK TYPE: EARLOOP: 175MM X 95MM, 50 PCS

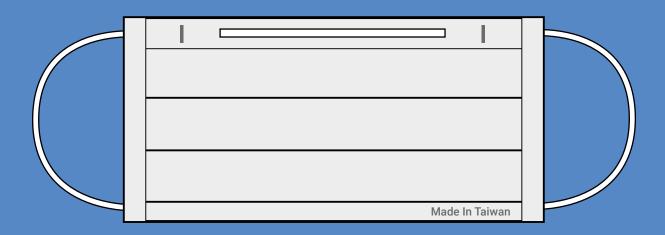
BATERIAL FILTRATION EFFICACY (BFE) ≥ 99.0%

MEET EN 14683:2019 TYPE II AND CNS 14774:2018 MEDICAL MASK STANDARD.

MATERIAL AND PRODUCT STRUCTURE

THIS PRODUCT CONSISTS OF AN OUTER LAYER, AN INNER LAYER, A FILTER LAYER, A BENDABLE NOSE CLIP AND EARLOOPS.

Procedure mask (Level 1)



Material: Non-woven fabric, melt-blown non-woven fabric

Description: Three-layers, flat-folded mask with ear loops and a nose

piece.

Size: Unisex Size for Adult

Standard: Meet ASTM F2100 LEVEL 1 Standard



Applications

the mask is ideal for both women and men, suitable for school and daily use. It provides protection against dust, automobile exhaust, pollen, etc.





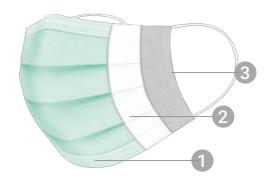








Testing Report



- 3 Inner Barrier Layer non-woven fabric
- 2 Middle Barrier Layer melt-blown non-woven fabric
- Outer Barrier Layer
 non-woven fabric

ASTM F2100 LEVEL 1

CTUAL TESTING RESULT≥99%	BACTERIAL FILTRATION EFFICIENCY (ASTM F2101) ≥95%(ACTU
≥80 mmH	FLUID RESISTANCE REQUIREMENTS (ASTM F1862)
CLASS	FLAMMABILITY TESTING (16 CFR 1610)
≥95%	PARTICLE FILTRATION TESTING (ASTM F2299)
<5 mm H ₂ 0/cm	AIR FLOW RESISTANCE (I.E., BREATHABILITY) ASSESSMENT (EN14683 ANNEX C)

IN VITRO CYTOTOXICITY (ISO 10993-5)	PASS
SKIN SENSITIVITY (ISO 10993-10)	PASS
SKIN IRRITATION (ISO 10993-10)	PASS

Surgical mask (Level 2)



Material: Non-woven fabric, melt-blown non-woven fabric

Description: Three-layers, flat-folded mask with ear loops and a nose

piece.

Size: Unisex Size for Adult

Standard: Meet ASTM F2100 LEVEL 2 Standard

- Bacterial filtration efficiency ≥98% (ACTUAL TESTING RESULT≥99.7%)
- fluid resisitance requirements ≥120 mm Hg
- particle filtration testing ≥98%
- · SKin sensitivity- pass



Applications

the mask is ideal for both women and men, suitable for school and daily use. It provides protection against dust, automobile exhaust, pollen, etc.





Industrial purpose/ PPE



Healthcare and CCRC



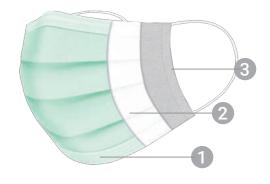


Laboratory



Test Centres

Testing Report



- 3 Inner Barrier Layer non-woven fabric
- 2 Middle Barrier Layer melt-blown non-woven fabric
- Outer Barrier Layer
 non-woven fabric

ASTM F2100 LEVEL 2

ERIAL FILTRATION EFFICIENCY (ASTM F2101) ≥98%(ACTUAL TESTING RESULT	
FLUID RESISTANCE REQUIREMENTS (ASTM F1862)	≥120 mmHg
FLAMMABILITY TESTING (16 CFR 1610)	CLASSI
PARTICLE FILTRATION TESTING (ASTM F2299)	≥98%
AIR FLOW RESISTANCE (I.E., BREATHABILITY) ASSESSMENT (EN14683 A	NNEX C) <6 mm H ₂ 0/cm ²
BIOCOMPATIBILITY ASSESSMENT	
IN VITRO CYTOTOXICITY (ISO 10993-5)	PASS
SKIN SENSITIVITY (ISO 10993-10)	PASS
SKIN IRRITATION (ISO 10993-10)	PASS

Surgical mask (Level 3)



Material: Non-woven fabric, melt-blown non-woven fabric

Description: Three-layers, flat-folded mask with ear loops and a nose

piece.

Size: Unisex Size for Adult

Standard: Meet ASTM F2100 LEVEL 3 Standard

- Bacterial filtration efficiency ≥98% (ACTUAL TESTING RESULT≥99.7%)
- fluid resisitance requirements ≥160 mm Hg
- particle filtration testing ≥98%
- SKin sensitivity- pass



Applications

the mask is ideal for both women and men, suitable for school and daily use. It provides protection against dust, automobile exhaust, pollen, etc.





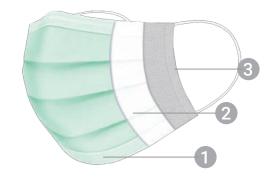








Testing Report

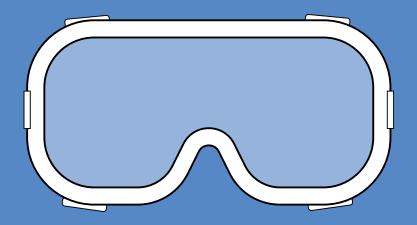


- Inner Barrier Layer non-woven fabric
- 2 Middle Barrier Layer melt-blown non-woven fabric
- Outer Barrier Layer
 non-woven fabric

ASTM F2100 LEVEL 3

BACTERIAL FILTRATION EFFICIENCY (ASTM F2101)	≥98%(ACTUAL TESTING RESULT ≥99.7%)
FLUID RESISTANCE REQUIREMENTS (ASTM F1862)	≥160 mmHg
FLAMMABILITY TESTING (16 CFR 1610)	CLASSI
PARTICLE FILTRATION TESTING (ASTM F2299)	≥98%
AIR FLOW RESISTANCE (I.E., BREATHABILITY) ASSESSMENT (EN14683 ANN	NEX C) <6 mm H ₂ 0/cm ²
BIOCOMPATIBILITY ASSESSMENT	
IN VITRO CYTOTOXICITY (ISO 10993-5)	PASS
SKIN SENSITIVITY (ISO 10993-10)	PASS
SKIN IRRITATION (ISO 10993-10)	PASS

Goggle/ Glasses

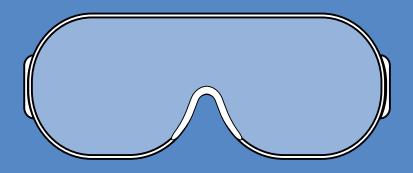


Product: Goggle
Material: Plastic

Description: Full cover

Size: Unisex Size

Standard: ANSI Z87.1-2015, EN 166: 2001.



Product: Glasses
Material: Plastic

Description: Full cover

Size: Unisex Size

Standard: ANSI Z87.1-2015, EN 166: 2001.

Goggle

Feature

- Meet standard ANSI Z87.1-2015, EN 166: 2001.
- · Anti-Fog Eye Protection for Classroom Lab, Home, and Workplace Safety.
- Safety Goggle Chemical Splash and Impact Resistant Goggle Clear Anti-Fog/Anti-Scratch Coating Protective Eyewear
- · Adjustable head belt: The elastic band design to facilitate the fastening of the head circumference. It has wide space and it's suitable for various head circumferences.



Glasses

Feature

- Meet standard ANSI Z87.1-2015, EN 166: 2001.
- Protective: Eye injuries in the workplace and homeplace occur often. When workers use stud finder or wood moisture meter to finish their work, they are at risk of being hit by flying objects, debris, particles or airborne dust.
- · Anti fog: Our anti fog safety glasses contain anti-fog coating, the lenses are not easy to fog when exposed to water vapor.
- Light weight: The body of these wide safety lasses is made entirely from lightweight plastic.



Certificate

Glasses

Test Result

1. EN 166:2001 / BS EN 166:2002 Personal eye-protection - Specifications Personal eye-protection - Specifications

Clause
7.2.4 Protection Against Droplets and Splashes of Liquids

Result See Finding

Eye-protectors for use against droplets (goggles) and splashes of liquids (face-shields) shall be tested in accordance with the methods specified in clause 12 of EN 168:2001.

finding
The intrusion of color did not into the circles of the eye area after the test.

2. ANSI/ISEA Z87.1-2015 American National Standard for Occupational and Educational Personal Eye and Face Protection Devices

See Finding

Section
8.1 Droplet and Splash Hazard
8.1.1 Goggles
When tested with reference to Section 9.17.1, the droplets and/or liquid splash shall not cause a red coloration within either of the two circles de-scribed in the test method.

finding
The intrusion of color did not into the circles of the eye area after the test.

Remark: 1. Samples were provided by applicant and samples were randomly selected to be assessed.

2. The content of this report is invalid if it is not presented as the entire report.

- Picture(s)





Photo "A": Appearance of sample (front view)

Photo "B": Appearance of sample (side view)

Goggle

TEST REPORT

Hardline Laboratory

Report No.: YA40084/2020

Page: of 2

Test Result

1. EN 166:2001 / BS EN 166:2002 Personal eye-protection – Specifications Personal

Result

Clause
7.2.4 Protection Against Droplets and Splashes of Liquids
Eye-protectors for use against droplets (goggles) and splashes of liquids (face-shields) shall be
tested in accordance with the methods specified in clause 12 of EN 168:2001.

ANSI/ISEA Z87.1-2015 American National Standard for Occupational and Educational Personal Eye and Face Protection Devices

Section 8.1 Droplet and Splash Hazard

8.1.1 Goggles
When tested with reference to Section 9.17.1, the droplets and/or liquid splash shall not cause a red coloration within either of the two circles de-scribed in the test method.

Remark: 1. Samples were provided by applicant and samples were randomly selected to be assessed.

2. The content of this report is invalid if it is not presented as the entire report.





Photo "A": Appearance of sample (front view)

Photo "B": Appearance of sample (side view)

- End of Report -

■ Contact Information

We'd love to hear from you! For general inquiries, contact us at

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Phone: +886-2-2562-6070 **FAX:** +886-2-2571-2248

Email: info@atomhealth.com