

# Procedure Masks

Paneffort offers procedure masks in all three ASTM levels with each mask providing the optimal level of protection against light, moderate and heavy levels of spray, splatter and aerosols.

## Mask Features

Made from high quality non-woven fabric, the outer layer of the Paneffort Procedure Mask offers maximum protection and fluid resistance while the inner layer is designed to be soft and gentle on the skin.

- Low differential pressure offers excellent breathability
- Adjustable nose piece and full length ear loops
- Does not contain components made from rubber latex
- Made in Cambodia, TAA Cambodia



ASTM Standards	Level 1	Level 2	Level 3
Fluid Resistance, mmHg	80	120	160
BFE	≥ 95%	≥ 98%	≥ 98%
PFE, @0.1 micron	≥ 95%	> 98%	> 98%
DELTA P, mm	< 4.0	< 5.0	< 5.0
Flame Spread	Class 1	Class 1	Class 1

Item No.	Description	Pkg.
3PML1-EXEL-11	ASTM Level 1 3Ply Procedure Mask. Blue.	2,000/cs
3PML2-EXEL-11	ASTM Level 2 3Ply Procedure Mask. Blue.	2,000/cs
3PML3-EXEL-11	ASTM Level 3 3Ply Procedure Mask. Blue.	2,000/cs



## Paneffort 3ply Isolation Face Mask

Recommended for: Decontamination, Emergency, ICU, Food Services, Airborne and Contact Precautions and Droplet Precautions. Meets ASTM F2100-11 Level 2 standards. Our three layer design promotes fluid resistance and bacterial challenge.

- Material tested against ASTM F2100-11 for fluid penetration
- Bacterial filtration efficiency  $\geq 98\%$ .
- Particulate filtration efficiency  $\geq 98\%$ .
- Provides fluid resistance  $\geq 120\text{mmHg}$
- Non-Sterile
- Medical use
- "Super-soft" interior lining



### Paneffort 3ply Isolation Face Mask

Our 3ply isolation face mask meets ASTM Level 2 standards providing barrier protection for low to moderate levels of aerosols, spray and/or fluids.

- Material tested against ASTM F2100-11 for fluid penetration
- Bacterial filtration efficiency  $\geq 98\%$ .
- Particulate filtration efficiency  $\geq 98\%$ .
- Provides fluid resistance  $\geq 120\text{mmHg}$
- Non-Sterile
- Medical use
- "Super-soft" interior lining





## Paneffort 3ply Isolation Face Mask

Our 3ply isolation masks are sealed in individual bags of 10. Each box has 5 bags of 10 for a total Of 50 bags per box. This provides greater utility And best practices in distributing masks.

- **Product** 3ply Surgical Mask. Meets ASTM F2100-19 Level 2 standards
- **Material** Melt-blown & Spunbond Polypropylene
- **Packed** 10/bag, 5 bag/box, 40 box/case, Total 2,000 pcs, 30cases/pallet
- **Carton** Measure 52\*40\*40cm, GW 20.5 lb
- **Origin** Made in Cambodia, TAA Compliant
- **Code** 3PML2-EXEL-11, One size, Blue





## Packaging & Shipping



### Box Details

Contains 50 masks. 5 sealed bags of 10. Measure 52\*40\*40cm, GW 20.5lb

### Case Details

Contains 40 boxes (2,000 masks total) Measure 19\*10\*10cm, GW .5lb



## Packaging and Unit of Measure

Our case shippers contain 40 boxes of masks stacked two layers high of 20 boxes each. Our case cartons are high quality commercial construction. They are shipped 30 cases on a pallet total pallet and 24 pallets to a truck.

- Product 3ply Surgical Mask ASTM Level 2
- Packed 10/bag, 5 bag/box, 40 box/case, total 2,00
- 30 cases to pallet / 26 pallets to a truck
- Case Measure 52\*40\*40cm, GW 20.5 lb
- Origin Made in Cambodia, TAA Compliant
- Code 3PML2-EXEL-11, One size, Blue

## Successful 2020 Medical Device Establishment Registration

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2020:

Registration Number:

Owner Operator Number: 10075871

Pan effort (cambodia) Garment Co., Ltd.

National Road No 2, Kleang Sambatt

Pot Sar Ward

CAMBODIA 21309

If you do not see a registration number assigned to the establishment and your establishment previously had one, please send an email to [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov) and include the registration number you believe is assigned to your establishment. We will review and determine if a duplicate registration has been created for your establishment.

Your registration is valid until December 31, 2020. Registration for 2021 will be conducted between October 1 and December 31, 2020.

Please note that registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to the CDRH Registration and Listing Helpdesk at [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov).

CDRH Registration and Listing Helpdesk  
Imports & Registration and Listing Team  
Division 2 Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration





**DRLM**  
Device Registration & Listing Module

DRLM Home > View Proprietary Names and Labeling

View Proprietary Names and Labeling

Proprietary Names

Listing Number	Premarket Submission Number
D416353	

Show 10 per page

Filter:

[Clear Sort and Filter](#)

Proprietary Name	Confidential Flag	Device labeled for use	Device Identifier	Uploaded Labels
Paneffort Isolation Face Mask	N			

Showing 1 to 1 of 1 entries

Previous1Next

Close And Return

## Products



**Test Report No.:** 244252816c 001

Page 1 of 5

**Client:**

**PANEFFORT(CAMBODIA)GARMENT CO.,LTD.**

Address: NATIONAL ROAD NO. 2, PHUM KHLANG SOMBAT, KUM PUTSOR,  
SROK BATI, TAKEO PROVINCE,CAMBODIA

Contact Person: Iris Du

**Sample Description As Declared :**

No. Of Sample	: 80 pcs
Product Description	: Disposable Mask
Colour	: Blue
Lot No./ Batch code	: 202007
Country of Origin	: Cambodia
Sales Destination	: USA
Buyer	: Product Source Group
Manufacturer	: PANEFFORT(CAMBODIA)GARMENT CO., LTD.
Test Type	: Partial test
Product Type	: Single shift use only
Claimed Classification	: Level 2

**Sample obtaining method:** Sending by customer

**Sample Receiving date:** 2020-07-15

**Delivery condition:** Apparent good, Samples tested as received

**Test Period:** 2020-07-15 to 2020-07-23

**Test specification:**

**Test result:**

ASTM F2100-19 Standard Specification for  
Performance of Materials Used in Medical Face Mask

Please refer to next page

**For and on behalf of**

**TÜV Rheinland (Shanghai) Co., Ltd.**

2020-07-23

Nicky Chen / Project Manager

Date

Name/Position

*Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed.  
This test report 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 safety mark on this or similar products.*



Test Report No.: 244252816c 001

Page 2 of 5

### Summary of test results

Clause	Test Description	M001
9.1	Bacterial filtration efficiency	M
9.2	Differential Pressure	M
9.4	Resistance to Penetration by Synthetic Blood	M
9.5	Flammability	M

Note : M = Meet Performance Standard  
# = No Specified Requirement  
N/A = Not Applicable

F = Below Performance Standard  
\* = No Submitted Information

### Material list

Material No.	Material	Color/Pattern	Location
M001	Whole Product	Blue	Mask

Test Report No.: 244252816c 001

Page 3 of 5

**1. Bacterial filtration efficiency**

Test method : ASTM F2100-19e1 Clause 9.1

Requirement : Level 2: ≥98%

**M001**

	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
B (%)	>99.8	>99.9	>99.9	>99.9	>99.9
Conclusion	Pass				

**2. Differential Pressure**

Test method : ASTM F2100-19e1 Clause 9.2

 Requirement : Level 2: <6.0 mmH<sub>2</sub>O/cm<sup>2</sup>
**M001**

Specimen	Pressure (mmH <sub>2</sub> O/cm <sup>2</sup> )					
	Area 1	Area 2	Area 3	Area 4	Area 5	Mean
1	5.7	4.9	5.3	5.1	5.2	5.2
2	5.1	5.2	5.2	5.2	5.3	5.2
3	5.1	5.1	5.7	5.1	5.2	5.2
4	5.5	5.7	5.2	5.2	5.8	5.5
5	5.3	4.9	5.2	5.3	5.2	5.2
Conclusion	Pass					

**3. Resistance to Penetration by Synthetic Blood**

Test method : ASTM F2100-19e1 Clause 9.4

Requirement : Level 2: 120 mm Hg no penetration

**M001**

Specimen	Wetness	Specimen	Wetness	Specimen	Wetness	Specimen	Wetness
1	N.P.	9	N.P.	17	N.P.	25	N.P.
2	N.P.	10	N.P.	18	N.P.	26	N.P.
3	N.P.	11	N.P.	19	N.P.	27	N.P.
4	N.P.	12	N.P.	20	N.P.	28	N.P.
5	N.P.	13	N.P.	21	N.P.	29	N.P.
6	N.P.	14	N.P.	22	N.P.	30	N.P.
7	N.P.	15	N.P.	23	N.P.	31	N.P.
8	N.P.	16	N.P.	24	N.P.	32	N.P.
Conclusion	Pass						

Remark: N.P. = no penetration

Test Report No.: 244252816c 001

Page 4 of 5

#### 4. Flammability

Test method : ASTM F2100-19e1 Clause 9.5  
Requirement : Level 2: Class 1

	<u>M001</u>
Fabric type	Plain surface
Conditioning	<u>Sample as received</u>
Burn side	Face
Burn direction	Length
Specimen 1	DNI
Specimen 2	DNI
Specimen 3	DNI
Specimen 4	DNI
Specimen 5	DNI
Average	DNI

Classification : Class 1, Normal flammability

Remark: DNI = Did not ignite.  
IBE = Ignite but extinguished.  
\_.\_sec = Actual burn time in seconds measured and recorded by the timing device.

Test Report No.: 244252816c 001

Page 5 of 5

Sample Photos:



---END---



[illegible]

# Paneffort 3ply Isolation Face Mask

## Technical Specification Sheet

### Key Features

Meets ASTM F2100-19 Level 2 standards

The full-width nosepiece guarantees a proper fit

High quality spandex ear loops provide quality fit

Features soft face feel utilizing fluid resistant, polypropylene inner and outer.

BFE $\geq$ 95% PFE $\geq$ 95%

Fluid resistance pressure  $\geq$ 80mmHg

Non-Sterile

Medical use

### Material Composition

Three (3) ply, Pleated

Non-woven fabric and melt-blown fabric

Nose clip - polyethylene plastic material

Ear loops - terylene, spandex

Splash resistant, Fluid resistant

Fiberglass free, Latex free, Hypoallergenic

### Technical Specifications

Three (3) Ply construction.

3 pleat fold allows the user to expand the mask so it covers the area from the nose to the chin.

L\*W - 17.5\*9.5cm

Nose clip length $\geq$ 8.0 cm

BFE $\geq$ 95% PFE $\geq$ 95%

Differential pressure <5mm H<sub>2</sub>O/cm<sup>2</sup>

Splash resistance pressure  $\geq$ 80mmHg

Flammability: Flammability Rating Class I

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 seconds after removal from the flame.

Non-Sterile

## Applications Scope

The transmission of infectious agents during surgical procedures in operating theaters and other medical settings can occur in several ways. Sources are, for example, the noses and mouths of members of the surgical team. The main intended use of surgical masks is to protect the patient from infectious agents and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids.

Protects both the patient and the operating personnel from the transfer of microorganisms, bodily fluids and particulate material during medical procedures.

To be worn over the mouth and nose of medical staff to prevent the spread of respiratory tract microorganisms into open wounds during surgery and to prevent the bodily fluids of the patients from spreading to the medical staff. Performing two-way biological protection.

\*Intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

Always follow User Instructions and use only in the indicated manner.

## Caution

DO NOT use in any manner not indicated in the

## Approvals and Standards

Meets ASTM F2100-19 Level 2 standards

## User Instructions.

### 1. Visual inspection before use

Inspect mask if it's in the original packaging, which is protected against mechanical damage and contamination before use.

Check the end of shelf time and use the mask before the "use by" date specified on packaging.

Inspect mask before each use to ensure that it is in good operating condition. Examine all the mask parts for signs of damage including ear loops and nose clip etc. The mask should be disposed of immediately upon observation of damaged or missing parts.

### 2.Fitting Instructions

Must be followed each time the mask is worn.

Before fitting device, ensure hands are clean.

I. The colored side/the side with folds should face outwards with the nose clip uppermost.(Image 1)

II. Position the ear loops around both ears.(Image 2)

III. Extend the disposable mask to fully cover mouth, nose and chin.(Image 3)

IV. Mold the nose clip over nose bridge and the disposable mask should fit snugly over the face. (Image 4)

V. Once the mask is firmly in place, cover the mask with both hands to test to ensure its tightness. Please cover the mask with both hands and exhale. If you feel gas leaking from the nose clip,

Figure 1



### 3. Caution during use

Always be sure that the complete product is:

- Suitable for the application
- Fitted correctly
- Worn during all periods of exposure
- Replaced when necessary

The body of the mask is not touched by the fingers/hands of the wearer.

A mask is worn covering the nose and mouth of the wearer, at no time a mask is hanging around the neck of the wearer.

Hands are disinfected (full hand disinfection) after mask removal.

A used mask should be disposed of when no longer needed.

When there is further need for protection a new mask should be put on.

Leave the contaminated area immediately and contact supervisor if dizziness, irritation or other distress occurs.

Do not alter, repair, wash, and abuse or misuse the mask.

The mask fully covers mouth, nose and chin; however, it will not prevent entry through other routes such as the skin or eyes, which would require additional personal protective equipment (PPE).

The filtration efficiency of the mask may decrease in the presence of oily mists.

Replace the mask when it becomes dirty, damaged, or difficult to breathe through.

Maximum Operating Temperature: +50 degrees Celsius.

All mask should be used in accordance with local regulations.

### 4. After Use

Dispose of used product in accordance with applicable regulations.

The user must dispose of used products strictly in accordance with the regulation of medical waste.

### 5. Use Limitations

This mask does not supply oxygen. Do not use in atmospheres containing less than 19.5% oxygen.

Do not use when concentrations of contaminants are immediately dangerous to life and health.

The mask is designed for adults and professionals.

This product is not designed to be used by children.

Individuals with a compromised respiratory system, such as asthma or emphysema, should consult a physician and complete a medical evaluation prior to use.

### 6. Time Use Limitation

One shift/disposable/one-time use only.

Replace the mask when it becomes dirty, damaged, or difficult to breathe through.

As for any filter, service time will be limited by considerations of hygiene and increased breathing resistance due to filter loading.

### Shelf Life and Storage

2 years from the date of manufacture.

Production date on box in DD/MM/YYYY format.

Store mask in the original packaging, away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals.

Store mask against mechanical damage.

Store in temperatures between -4°F(-20°C) and +86°F(+30°C) and not exceeding 80% RH.