

COPPERX

4 Ply Medical Face Mask



COPPERX
4 Ply Medical Face Mask

The Best Defense Is A Good Offense
Pencegahan Yang Terbaik Bermula
Daripada Perlindungan Diri
最好的防守就是进攻



XV613 PRODUCT DATASHEET

Copper X 4 Ply Medical Face Mask

PHYSICAL DIMENSION

| DESIGN | FEATURES |
|----------|---|
| 4-layers | Hydrophobic Fluid Resistance (Antimicrobial Copper Coated) |
| | Hydrophobic Fluid Resistance (Antimicrobial Copper Coated) |
| | High Density Melt Blown Filter |
| | Moisture Absorbent Lint Free |



Product Specification & Instruction Use

Classification:

MSDS, Product Datasheet,
EN14683 Type IIR
ASTM Level 3

Product Material:

Copper Oxide Surface Coating
and Lint Free Fabric

Packaging Mode:

30pcs/box (Individual Packaging)

Physical Features

- Hypoallergenic
- 99% Antibacterial
(Proven to kill bacteria within 4 hours)
- 4 Layers Protection
- Quad Fold

- Store in dry, clean conditions in original packaging.
- Store away from direct sunlight, source of high temperature and solvent vapors.
- Store with the temperature range 0°C to +39°C and with relative humidity below 80%.
- Shelf life is 60 months from the date of manufacture when stored as stated above.
- Replace if damaged, heavily contaminated or in accordance with local practice.
- Hand and dispose of contaminated face mask with care and in accordance with national regulations.

ASTM-F2100 MASK PERFORMANCE

LEVEL
3

| | |
|---|---------|
| BFE (%) | >99 |
| ΔP (mm H ₂ O/cm ²) | <6.0 |
| PFE @0.1μ (%) | >99 |
| Fluid Resistance (mmHg) | 160 |
| Flammability | Class 1 |

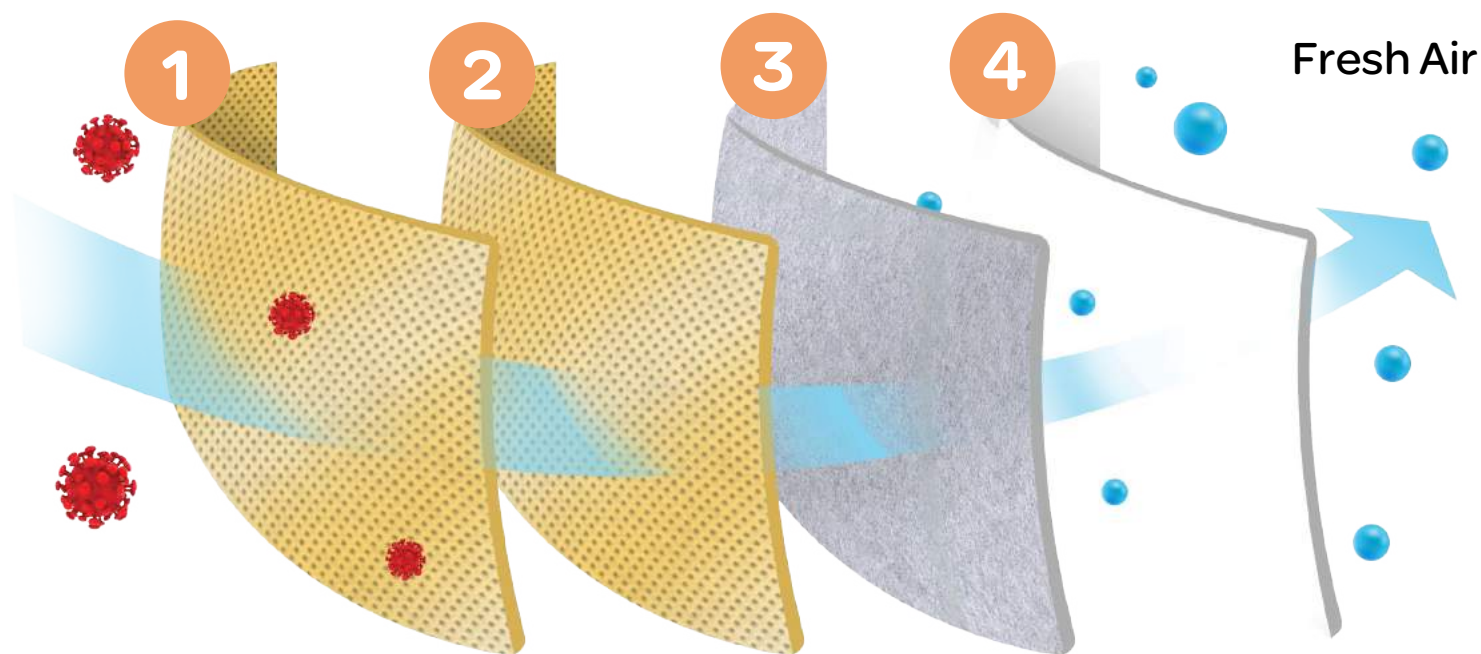
Instruction:



1. Place loop over the ears.
2. Ensure coloured layer to face out.
3. Adjust nose piece for comfort fit.



Copper X 4 Ply Face Mask Filter Layer



1. OUTER LAYER

Hydrophobic Fluid Resistance
(Antimicrobial Copper Coated)

2. SECOND LAYER

Hydrophobic Fluid Resistance
(Antimicrobial Copper Coated)

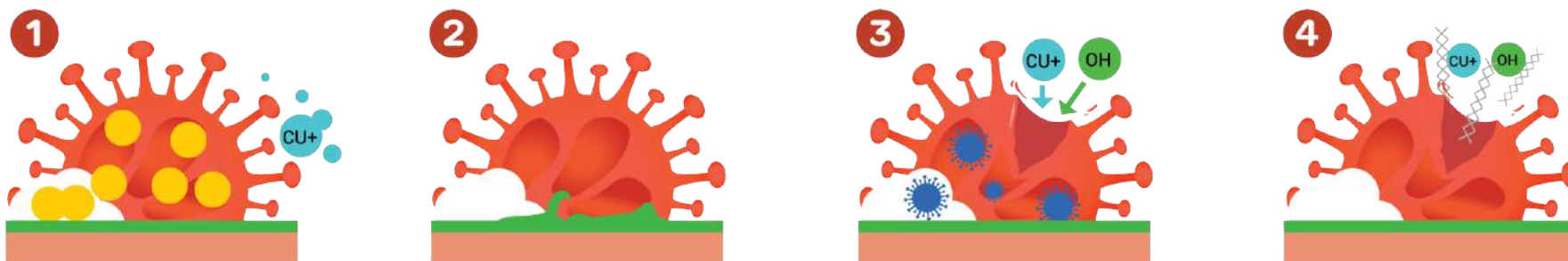
3. THIRD LAYER

High Density Melt
Blown Filter

4. INNER LAYER

Moisture Absorbent
Lint Free

ANTIMICROBIAL COATING TECHNOLOGY



Every piece of Copper X Medical Face Mask is coated with copper oxide surfaces at the outer and second layer which are consist of antimicrobial properties. It disrupts bacterial cell membranes such as infective protein including COVID-19.

By using Copper X Medical Face Mask, it is possible to reduce the virus by breaking down their protective proteins in order to prevent our health from being threaten.



Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Copper-oxide impregnated respiratory masks may significantly reduce the risk of SARS-CoV-2 cross-contamination

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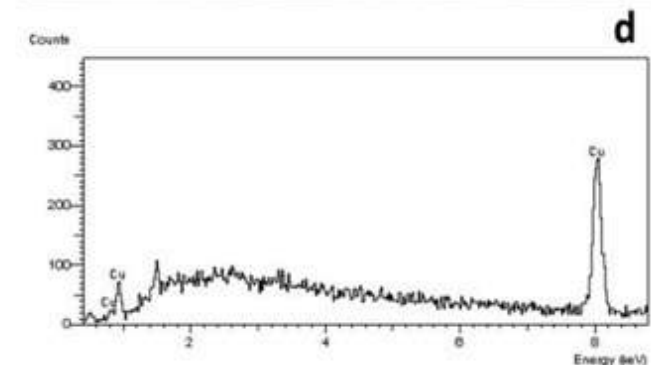
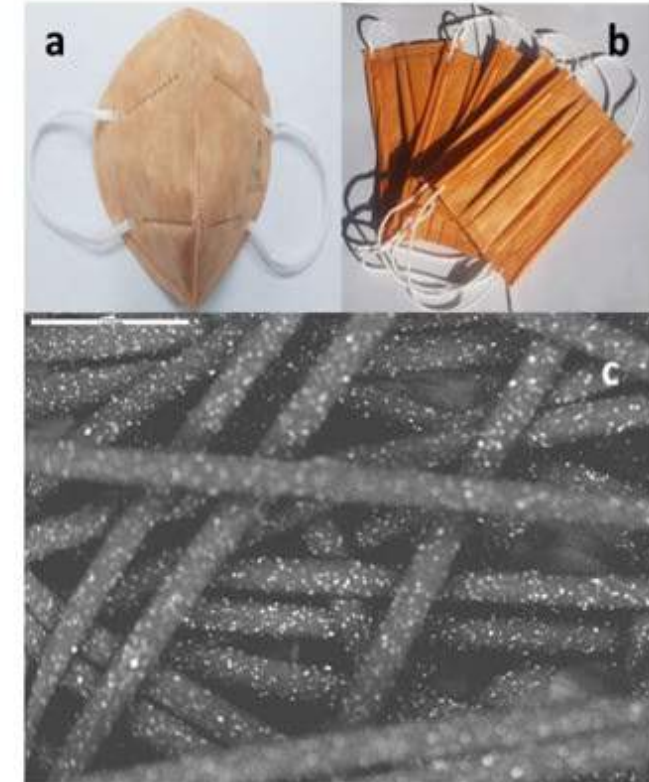
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Certificates and Test Reports (Antiviral Activity Test)



广东省微生物分析检测中心

GUANGDONG DETECTION CENTER OF MICROBIOLOGY
分析检测报告
REPORT FOR ANALYSES



报告编号 (Report No.) 2021FM00949R01 校验码 (Verification Code): 51864027

| | | | |
|--------------------------------------|--------------------------|-------------------------------------|----------------------|
| 样品名称 Name of Sample | 铜系抗菌抗病毒无纺布 | 检测类型 Test Type | 委托检测 |
| 委托单位 Applicant | 上海沪正实业有限公司 | 地址 Address | 上海闵行区新骏环路158号2A楼403室 |
| 样品来源 Sample Source | 委托方送检 | 样品数量 Sample Quantity | 50g |
| 样品规格和批号 Spec and Lot No of Sample | WH50S | 样品状态和特性 State and Characteristic | |
| 接样日期 Sample Received Date | 2021-01-14 | 检测完成日期 Completion Date | 2021-01-19 |
| 检测依据和方法 Test Standard and Method | ISO 18184: 2019 (E) | | |
| 检测项目 Item Tested | 抗病毒活性试验 | | |
| 检测结论 Test Conclusion | 该样品所检项目的实测数据见本检测报告续页。 | | |
| 备注 Remarks | 生产厂家: 上海沪正实业有限公司。由委托方提供) | | |

签发日期: 2021-01-19
Issue Date



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Editor

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Approver



广东省微生物分析检测中心

GUANGDONG DETECTION CENTER OF MICROBIOLOGY
分析检测结果
ANALYSIS AND TEST RESULT

报告编号 (Report No.): 2021FM00949R01

| 实验病毒及宿主 Virus and host cell | 实验序号 No. | 对原样未经抗病毒处理试样接种 0h 后 病毒滴度 Infectivity titre value immediate after inoculation of the reference specimen | 对原样未经抗病毒处理试样接种 24h 后 病毒滴度 Infectivity titre value after 24h contacting with the reference specimen | 试样经抗病毒处理试样接种 24h 后 病毒滴度 Infectivity titre value after 24h contacting with the test specimen |
|---|-------------|---|---|--|
| 甲型流感病毒 H1N1 宿主名称 MDCK 细胞 Influenza A virus H1N1 Host cell MDCK | 1 | 6.97 | 6.42 | 4.30 |
| | 2 | 6.87 | 4.67 | 4.30 |
| | 3 | 6.87 | 4.80 | 4.30 |
| 平均病毒滴度对数值 Average logarithm of infectivity titre value | | 6.90 | 6.41 | 4.33 |
| 抗病毒活性值 Antiviral activity value | | | 2.53 | |
| 抗病毒活性率 (%) Antiviral activity rate (%) | | | 99.70 | |
| <以下空白 Empty> | | | | |

抗病毒活性值
Antiviral activity value

抗病毒活性率 (%)
Antiviral activity rate (%)

2.53

99.70

Certificates and Test Reports (SGS)

SGS

检测报告

ASH20-073199-01

发布日期: 2020年 12月 9日

| | | |
|--------|--------------------------|--------------------|
| 检测样品描述 | SGS样品ID SGS Sample ID | 描述 Description |
| 编号 | ASH20-073199.001 | 袋装样品 Sample in Bag |

检测结果 Test Result

检测要求: 对所提交样品进行振荡接触时间为24小时的抗菌效果实验
Test Item: Determine the antimicrobial activity of submitted sample in 24 hours

检测方法: ASTM E 2149-2013a 在动态接触条件下抗菌剂抗菌活性测定的
Test Method: 标准试验方法
ASTM E 2149-2013a Determining the Antimicrobial Activity of Antimicrobial Agents

ASH20-073199.001

| | | |
|------------------------------|--|--|
| 检测菌种 Test Organism | 金黄色葡萄球菌 ATCC 6538 Staphylococcus aureus ATCC 8 | |
| | "0小时"接触时间获得的细菌数 (CFU/mL) The number of bacteria recovered from 0h Contact Time (CFU/mL) | "24小时"接触时间获得的细菌数 (CFU/mL) The number of bacteria recovered from 24h Contact Time (CFU/mL) |
| 样品 (1g) Sample (1g) | / | < 30 |
| 只接种对照样 Inoculum only control | 2.7x10 ⁵ | 1.5x10 ⁶ |
| 细菌减少率 (%) Reduction (%) | >99 | |

检测菌种 Test Organism 肺炎克雷伯氏菌 ATCC 4352 Klebsiella pneumoniae ATCC 4

| | | |
|------------------------------|--|--|
| | "0小时"接触时间获得的细菌数 (CFU/mL) The number of bacteria recovered from 0h Contact Time (CFU/mL) | "24小时"接触时间获得的细菌数 (CFU/mL) The number of bacteria recovered from 24h Contact Time (CFU/mL) |
| 样品 (1g) Sample (1g) | / | < 30 |
| 只接种对照样 Inoculum only control | 2.8x10 ⁵ | 1.4x10 ⁷ |
| 细菌减少率 (%) Reduction (%) | >99 | |

检测菌种 Test Organism 大肠杆菌 Escherichia coli 8099

| | | |
|------------------------------|--|--|
| | "0小时"接触时间获得的细菌数 (CFU/mL) The number of bacteria recovered from 0h Contact Time (CFU/mL) | "24小时"接触时间获得的细菌数 (CFU/mL) The number of bacteria recovered from 24h Contact Time (CFU/mL) |
| 样品 (1g) Sample (1g) | / | < 30 |
| 只接种对照样 Inoculum only control | 2.8x10 ⁵ | 1.4x10 ⁷ |
| 细菌减少率 (%) Reduction (%) | >99 | |

备注 Remark 细菌减少率的计算采用了只接种对照的数据。
The reduction calculations are based on values from inoculum only control.

| | | |
|------------------------|---|------------------------|
| SGS | | |
| 检测报 告 | ASH20-073199-01 | 发布日期: 2020年 12月 9 日 |
| 样品照片: Sample Photo: |  | |
| | ASH20-073199-001 | |
| | 该照片只针对SGS原始报 告 Photo are used for SGS original report | |
| | *** 结 束 *** *** End of Report *** | |

>99

细菌减少率 (%) Reduction (%)

Certificates and Test Reports (MDA)

No. Pendaftaran: **GA4308421-58036**
Registration No.:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan **Face Mask**
Medical Device Name

Kelas **CLASS A** Jenama **Bergamot**
Class Brand

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **BERGAMOT SDN.BHD 31, JALAN BALAKONG JAYA 4, TAMAN INDUSTRI**
Name and address of manufacturer **BALAKONG JAYA,, 43300, SERI KEMBANGAN, SELANGOR, MALAYSIA**

APPENDIX

| NO | NAME AS PER DEVICE LABEL | IDENTIFIER | BRIEF DESCRIPTION OF ITEM |
|----|---|------------|---|
| 1 | Bergamot 3- Ply Face Mask (Ear Loop) | B0501 | Bergamot 3- Ply Face Mask (Ear Loop) |
| 2 | Bergamot 3- Ply Face Mask (Tie On) | B0502 | Bergamot 3- Ply Face Mask (Tie On) |
| 3 | Bergamot 3- Ply Face Mask (Head Loop) | B0507 | Bergamot 3- Ply Face Mask (Head Loop) |
| 4 | Bergamot 3- Ply Face Mask Basic Medical | B0519 | Bergamot 3- Ply Face Mask Basic Medical |
| 5 | Bergamot 4- Ply Face Mask (Ear Loop) | B0504 | Bergamot 4- Ply Face Mask (Ear Loop) |
| 6 | Bergamot 4- Ply Vanscent Face Mask (Ear Loop) | VS8011 | Bergamot 4- Ply Vanscent Face Mask (Ear Loop) |
| 7 | Bergamot Copper X 4-Ply Medical Face Mask (Earloop) | X351B | Bergamot Copper X 4-Ply Medical Face Mask (Earloop) |

"End Of Product List"

TEST REPORT

TEST RESULTS

1. Immobilized Antimicrobial Agents Under Dynamic Contact
(ASTM E2149)

Test Organism: Staphylococcus aureus ATCC 6538
Klebsiella pneumoniae ATCC 4352
Specimen Weight: 1.0 g
Condition of Incubation: 1H +/- 5 min at Room Temperature, shake at 150 rpm in 50mL working solution of bacterial inoculum
Tested Sample: Submitted sample as received

Results:

| Test Organism | Staphylococcus aureus ATCC 6538 | Klebsiella pneumoniae ATCC 4352 |
|---------------|----------------------------------|----------------------------------|
| A | 5.5 x 10 ³ cfu/sample | 1.4 x 10 ⁴ cfu/sample |
| B | 2.1 x 10 ⁵ cfu/sample | 2.0 x 10 ⁵ cfu/sample |
| % Reduction | 97.4% | 93.0% |

Remark:

cfu = colony forming units

% Reduction: (B-A)/B*100

Where A = CFU/ml for the flask containing the test specimen after the specified contact time.

Where B = CFU/ml for the "Inoculum only" flask after the specified cor time.

Joice Anne

Joice Anne Bengzon Pena
Laboratory Executive

Dr. Chen Huayl

Dr. Chen Huayl
Assistant General Manager

END OF TEST REPORT

Immobilized Antimicrobial Agents Under Dynamic Contact Test (ASTM E2149)

| Test Organism | Staphylococcus aureus ATCC 6538 | Klebsiella pneumoniae ATCC 4352 |
|---------------|---------------------------------|---------------------------------|
| | | |
| % Reduction | 97.4% | 93.0% |

Round Earloop Design

- Comfortable Lining and Eliminates Pressure
- Elastic Earbands
- Ultra Comfort - Gentle Earloops

Ultrasonic Welding

- Firm Anti-Off Mesh Structure
- High-Quality Spot-Welding Filter Layer



Ultimate Fitting

- Aluminium Nose Strip
- Designed for All Facial Structure
- Extra Protection

Quad Fold Design

- Extra Breathability
- Comfort Design
- Secure Protection



WHY **COPPERX** ANTI-BACTERIAL FACE MASK

4 Ply Medical Face Mask

- 4 Ply Medical Face Mask
- EN 14683 Type IIR (Europe Standards)
- ASTM Level 3 (American Standards)
- Medical Device Authority (MDA) Approved
- Individual Packaging (Prevent Cross Contamination)
- Antimicrobial Copper Properties (Reduce or kill 99% Bacteria & Viruses within 4 hours) –Certified by ASTM E2149
- Quad Fold (Extra Breathability)
- Ultimate Fitting (Aluminium Nose Strip)
- Lint Free Material (Reduce potential discomfort or itchiness)

COPPERX

4 Ply Medical Face Mask



Contact Us



Copper X Website



Bergamot Website



Vanzo Asia Website

Manufactured By:

Bergamot Sdn Bhd

Unit 7 & 8, Jalan Sinaran 6, kawasan perindustrian
sinaran, 43000 Kajang, Selangor

Distributed By:

Vanzo Asia Sdn Bhd

No 10, Jalan Teknologi 3/1, Seksyen 3, Kota
Damansara, 47810 Petaling Jaya, Selangor