

Disposable Surgical Face Mask (Adult)

- BFE \geq 99% (3.0 microns)
- PFE \geq 98% (0.1 microns)
- Comfortable Elastic Earloop
- Individual Package
- Soft Breathable Material
- Perfect Fit Adjustable Nose Clip



50 pcs

Disposable Surgical Face Mask (Children)

- BFE \geq 98% (3.0 microns)
- PFE \geq 98% (0.1 microns)
- Comfortable Elastic Earloop
- Individual Package
- Soft Breathable Material
- Perfect Fit Adjustable Nose Clip
- Hypoallergenic

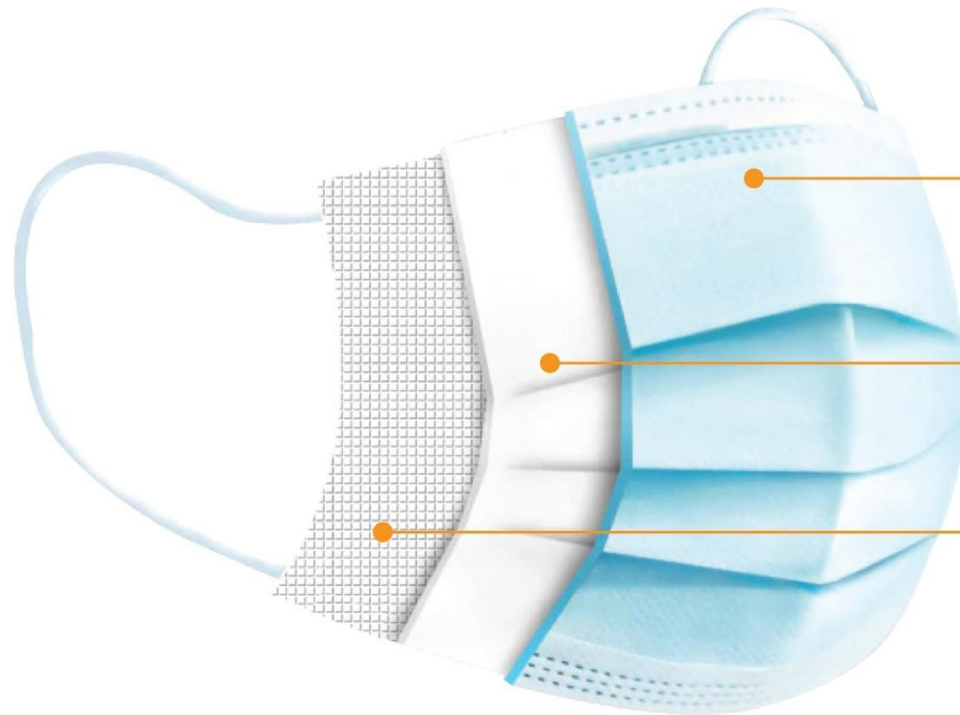


50 pcs

Made In Malaysia Quality

Quality Assured Consistency

MDA and ISO 13485:2016



NON-WOVEN 25gsm
Kalis air
Water resistant

MELT BLOWN NON-WOVEN 25gsm
Penapisan bakteria
Bacteria filtration

NON-WOVEN 25gsm
Lembut, selesa dan mudah bernafas
Soft, comfort and breathable

Box Packaging



Face Mask Size:	<i>170mm x 95mm</i>
Box Size:	<i>195mm x 100mm x 100mm</i>
Carton Box Size:	<i>523mm x 423mm x 426mm</i>
Gross Weight:	<i>10kg</i>
Box Packing:	<i>50pcs / box</i>
Carton Packing:	<i>40boxes / carton</i>

MDA ESTABLISHMENT

No. Siri: 005952
Serial No.:

ASAL ORIGINAL

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
MALAYSIA

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
LESEN ESTABLISHMEN
ESTABLISHMENT LICENCE
Seksyen 15(1) Akta 737
Section 15(1) of Act 737

No. Lesen : MDA-1105-WDP120
Licence No. :
Tarikh Sah Lesen : 02/07/2020 - 01/07/2023
Licence Validity Date :


Lesen adalah dengan ini diberi kepada:
Licence is hereby granted to: **RENTAS HEALTH SDN BHD**

yang beralamat di:
of: **NO 1 JALAN PERINDUSTRIAN DESA AMAN 1A,
INDUSTRI DESA AMAN, KEPONG
52200 KUALA LUMPUR,
WILAYAH PERSEKUTUAN KUALA LUMPUR.**

Sebagai:
as: **WAKIL DIBERI KUASA, PENGEDAR & PENGIMPORT
AUTHORIZED REPRESENTATIVE, DISTRIBUTOR &
IMPORTER**

Orang yang bertanggungjawab:
Person Responsible: **DANNY NG KOK AUN (I/C NO.: 840813-08-5841)**

Lesen ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan dibawahnya serta syarat-syarat seperti di Lampiran 1.
This licence is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 1.



AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

For the purpose of placing a medical device in the market: the manufacturer, Authorised Representative of foreign manufacturer, importer and distributor shall establish, maintain and implement appropriate quality management system that is commensurate with the role and function of the establishment.

Under the Medical Device Act (Act 737) and the Medical Device Authority Act 2012 (Act 738) all medical devices manufactured, imported, or distributed in Malaysia require a registration.

The Medical Device Authority (MDA) is a division of the Ministry of Health Malaysia (MOH) in charge of regulating medical device and its industry players in Malaysia.



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Report Code AR-20-XW-009534-01



Sample No 379-2020-08000058

TEST PROPERTY	RESULT	UNIT	REQUIREMENT
BACTERIAL FILTRATION EFFICIENCY (BFE)*			
ASTM F2101 : 19			
CUST 01			
INOCULUM SIZE	staphylococcus aureus usatcc:6538(5 x 10 ⁸ cfu/ml)		
MEDIUM USED	Tryptic soya agar		
FLOW RATE OF AEROSOL	28.3L/Minute		
SAMPLE EXPOSURE SIDE	faceside (100 x 10 0mm)		
MEAN PARTICLE SIZE OF CHALLENGE AEROSOL	2.9		
AVERAGE PLATE COUNT OF POSITIVE CONTROLS	2100		
AVERAGE PLATE COUNT OF NEGATIVE CONTROLS	0		
BACTERIAL FILTRATION EFFICIENCY AVG. %	98.3		
SAMPLE 1	98.3		Level 1 ≥ 95%
SAMPLE 2	98.1		Level 2 ≥ 98%
SAMPLE 3	98		Level 3 ≥ 98%
SAMPLE 4	98.6		
SAMPLE 5	98.4		
CONCLUSION:	PASS		

*Note: - Above tests has been subcontracted with Eurofins approved lab.

***** END OF REPORT *****



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Report Code AR-20-XW-009533-01



Sample No 379-2020-08000057

TEST PROPERTY	RESULT	UNIT	REQUIREMENT
BACTERIAL FILTRATION EFFICIENCY (BFE)*			
ASTM F2101 : 19			
CUST 01			
INOCULUM SIZE	staphylococcus aureus usatcc:6538(5 x 10 ⁸ cfu/ml)		
MEDIUM USED	Tryptic soya agar		
FLOW RATE OF AEROSOL	28.3 L/Minute		
SAMPLE EXPOSURE SIDE	faceside (100 x 10 0mm)		
MEAN PARTICLE SIZE OF CHALLENGE AEROSOL	2.9		
AVERAGE PLATE COUNT OF POSITIVE CONTROLS	2100		
AVERAGE PLATE COUNT OF NEGATIVE CONTROLS	0		
BACTERIAL FILTRATION EFFICIENCY AVG. %	98.0		
SAMPLE 1	97.7		Level 1 ≥ 95%
SAMPLE 2	98.2		Level 2 ≥ 98%
SAMPLE 3	98.1		Level 3 ≥ 98%
SAMPLE 4	97.9		
SAMPLE 5	98.2		
CONCLUSION:	PASS		

*Note: - Above tests has been subcontracted with Eurofins approved lab.

***** END OF REPORT *****



Why Is FDA So Important?

The Food and Drug Administration is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.



Why Is ISO So Important?

ISO 13485 ensures that manufacturers continue to design, develop, produce, install and deliver safely and in compliance with relevant regulatory requirements and the intended purpose of medical devices.

ISO 13485:2016 is the standard for a Quality Management System (“QMS”) for the design and manufacture of Medical Devices.

Certificate of Compliance

This certificate of compliance is hereby issued to the below applicant

Applicant — Pecca Leather Sdn Bhd
Address — No 1, Jalan Perindustrian Desa Aman
1A, Industri Desa Aman, Kepong,
52200 Kuala Lumpur, Malaysia.
Manufacturer — Same as above
Product Name — 1. Disposal Face Mask
2. Medical Face Mask
3. Surgical Face Mask
Applicable Directive(s) — Medical Devices Directive 93/42/EEC &
Personal
Protective Equipment Directive -
89/686/EEC
Testing laboratory — Eurofins
Test report Number — AR-20-XW-009533-01 &
AR-20-XW-009534-01
Test Standard — ASTM F2101 : 19



This Certificate of Compliance is issued under following conditions:

- 1- The product is declared by the applicant as complying with the applicable directives.
- 2 - EA has performed a review of the technical information of the product.
- 3- The applicant is required to inform EA of any changes to its product design and technical documentation.
- 4 - The CE mark may be used by the applicant, for this product, under the sole responsibility of the applicant.

Certificate Number: 21403

Initial Registration Date : 26/08/2020
Date of Certificate issue : 29/08/2020
Certificate Expiry: : 28/08/2023


Lavanya Raj
(Certification Manager)

Why Is CE So Important?

CE marking is an important procedure that guarantees product's conformity to EU regulations. Manufacturers, importers and distributors of non-food products are obligatory to provide the CE marking if they want to trade on EU/EAA markets.

Selling products without the CE mark is an economic offense that is punished differently by each Member State of European Union. Affixing CE marking on products that do not require the CE can also lead to penalties.



Why Is GDPMD So Important?

The objective of GDPMD is to ensure the quality, safety and performance of medical device which include but not limited to product sourcing and procurement; transportation and delivery; storage; installation, commissioning, service and maintenance, calibration and after sales service; tracking, documentation and record-keeping practices.

Thank You

Advancing Health Tech

Stay Safe, Stay Healthy With Ken-Air System Services Sdn Bhd