MASK CERTIFICATION

ISO CERTIFICATE

Mask Certification

Why 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

Medical Device Authority Malaysia

Business Partner of kiwa

Quality Management System Certificate
ISO 13485:2016

This is to certify that: Pecca Leather Sdn Bhd
No. 1, Jalan Perindustrian Desa Aman 1A
Industri Desa Aman
52200 Kepong
Kuala Lumpur

Holds Certificate No.: KICM/MDQ/20/0001

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

Design, Development and Manufacturing of Non-woven Jumpsuit, Isolation Full Set Cover, Isolation Cap Cover, Isolation Shoes Cover, Face Shield, 3-Ply and KN95/N95 Face Mask for Surgical/Medical and General Use.

For and on behalf of Kiwa International Certifications (M) Sdn. Bhd.

Signed by:

Managing Director
Dr Chan Yeik Kong

Effective Date: 14 August 2020

Expiry Date: 13 August 2023

CAB Registration No.: MDA/CAB-021

GDPMD CERTIFICATE

Mask Certification

Why GDPMD so important?

The objective of GDPMD is to ensure the quality, safety and performance of medical devices which include but are 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.

Certificate

CERTIFICATE OF CONFORMITY

Good Distribution Practice For Medical Device

This is to certify that: **Rentas Health Sdn Bhd**
No 1A, Jalan Perindustrian Desa Aman 1A,
Industri Desa Aman,
52200 Kepong,
Kuala Lumpur, Malaysia.

Holds Certificate No.: KICM/GD/20/0003

Has complied with the standard regulation requirement of GDPMD as stipulated MDA/RR No.01 November 2015 pursuant to Appendix 4, Third schedule of Medical Device Regulation 2012

Scope of Certification: Importer, Authorized Representative and Distributor for Import, Storage and handling, Warehousing, Distribution (including transportation) and Documentation (including traceability of medical devices)

List of devices dealt with by the establishment refer to Annex 1.

For and on behalf of Kiwa International Certifications (M) Sdn. Bhd.

Signed by:

Dr Chan Teik Ken
Managing Director

MDA CERTIFICATE

Mask Certification

Why MDA so important?

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.

No. Siri: 005052
Serial No.:

ASAL
ORIGINAL

PIHAK BERKUASA PERANTI PERUBATAN

MEDICAL DEVICE AUTHORITY

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

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

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

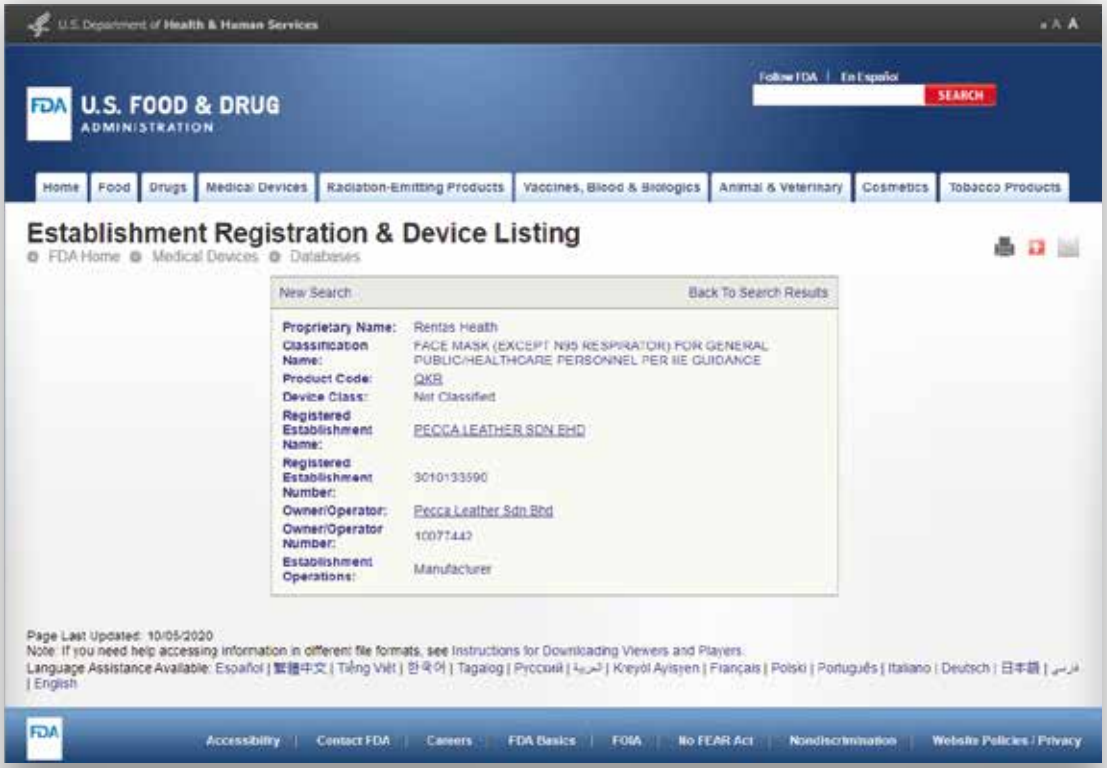
FDA CERTIFICATE

Mask Certification

Why 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.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=695162&lpcd=QKR



CE CERTIFICATE

Mask Certification

Why CE so important?

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

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

CE COMPLIANCE

Certificate of Compliance

This certificate of compliance is here by issued to the below applicant

Applicant — Pecca Leather Sdn Bhd
Address — No. 1 Jalan Perindustrian Desa Aman 1A, Industri Desa Aman, Kepong , Kuala Lumpur 52200, 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, AMCEN LAB & SIRIM
Test report Number — AR-20-XW-010093-03, AR-20-XW-010762-02, AMC/nMS2009/027,AMC/nMS2010/003, AR-20-XW-012197-01, AR-20-XW-012196-01, AR-20-XW-010060-01, AR-20-XW-010059-01, AR-20-XW-009890-02, R1142/20/B19/82, R1114/20/B19/02
Test Standard — ASTM F2100 : 2019 (Level 1,2 & 3)
EN 14683 : 2019 (Type I, II, IIR)
ISO 10993

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)

EURO ASSESSMENTS & CERTIFICATION LTD
Kemp House, 160 City Road, London, EC1V 2NX, United Kingdom

*Validity of the certificate is subjected to successful completion of surveillance audit on or before of due date.(In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawn).

Certificate Verification: Please verify certificate at https://www.euroassessments.co.uk
This certificate is the property of Euro Assessments & Certification Ltd and shall be returned immediately when demanded.

*The product liability rests with the manufacturer in accordance with their committed specifications and contractual obligations, including applicable standards. The CE mark shown above is for reference only and does not indicate accreditation. Euro Assessments does not accept any liability arising out of this certificate.

FILTRATION EFFICIENCY TESTING (BFE & PFE)

Bacterial Filtration Efficiency and Particle Filtration Efficiency are probably the most important tests to be conducted on medical textile products such as surgical masks, gowns or caps, as well as on air filters.

eurofins

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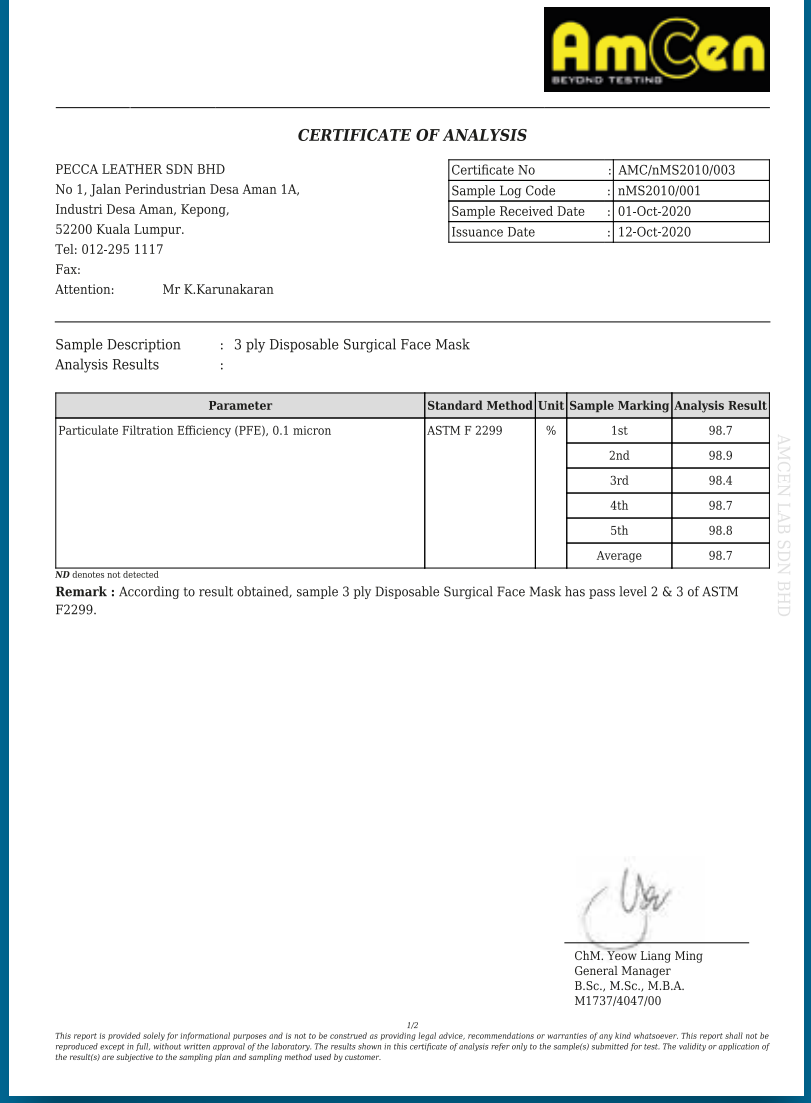
Report Code AR-20-XW-010762-01

Sample No 379-2020-08001148

TEST PROPERTY	RESULT	UNIT	REQUIREMENT
BACTERIAL FILTRATION EFFICIENCY (BFE)* ASTM F2101 : 19			
CUST 01			
INOCULUM SIZE	staphylococcusaureusatcc6538(5 x 10 *cfu/ml)		
MEDIUM USED	Tryptic soya agar		
FLOW RATE OF AEROSOL	28.3	L/Minute	
SAMPLE EXPOSURE SIDE	Face side		
MEAN PARTICLE SIZE OF CHALLENGE AEROSOL	3.1		
AVERAGE PLATE COUNT OF POSITIVE CONTROLS	2376		
AVERAGE PLATE COUNT OF NEGATIVE CONTROLS	Negative		
BACTERIAL FILTRATION EFFICIENCY AVG. %	99.2%	%	
SAMPLE 1	99.3%	%	Level 1 ≥ 95%
SAMPLE 2	99.2%	%	Level 2 ≥ 98%
SAMPLE 3	99.4%	%	Level 3 ≥ 98%
SAMPLE 4	99.0 %	%	
SAMPLE 5	99.1%	%	
CONCLUSION:	PASS		

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

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



AmCen BEYOND TESTING

CERTIFICATE OF ANALYSIS

PECCA LEATHER SDN BHD
No 1, Jalan Perindustrian Desa Aman 1A,
Industri Desa Aman, Kepong,
52200 Kuala Lumpur.
Tel: 012-295 1117
Fax:
Attention: Mr K.Karunakaran

Certificate No	:	AMC/nMS2010/003
Sample Log Code	:	nMS2010/001
Sample Received Date	:	01-Oct-2020
Issuance Date	:	12-Oct-2020

Sample Description : 3 ply Disposable Surgical Face Mask
Analysis Results :

Parameter	Standard Method	Unit	Sample Marking	Analysis Result
Particulate Filtration Efficiency (PFE), 0.1 micron	ASTM F 2299	%	1st	98.7
			2nd	98.9
			3rd	98.4
			4th	98.7
			5th	98.8
			Average	98.7

ND denotes not detected

Remark : According to result obtained, sample 3 ply Disposable Surgical Face Mask has pass level 2 & 3 of ASTM F2299.

ChM. Yeow Liang Ming
General Manager
B.Sc., M.Sc., M.B.A.
M1737/4047/00

1/2

This report is provided solely for informational purposes and is not to be construed as providing legal advice, recommendations or warranties of any kind whatsoever. This report shall not be reproduced except in full, without written approval of the laboratory. The results shown in this certificate of analysis refer only to the sample(s) submitted for test. The validity or application of the result(s) are subjective to the sampling plan and sampling method used by customer.

AMCEN LAB SDN BHD

SIRIM CERTIFICATE

Mask Certification

Why SIRIM so important?

SIRIM (Standard & Industrial Research Institute of Malaysia) is the national organisation for standards and quality and as a promoter of technological excellence in the Malaysian industry.

No Lesen : **PC005393**
Licence No :

LESEN PENSIJILAN BARANGAN
Product Certification Licence

SIRIM

SIRIM QAS International Sdn. Bhd. dengan ini menganugerahkan kepada
SIRIM QAS International Sdn. Bhd. hereby grants to

PECCA LEATHER SDN. BHD.
NO 1A, JALAN PERINDUSTRIAN DESA AMAN 1A
INDUSTRI DESA AMAN
KEPONG
52200 KUALA LUMPUR
WILAYAH PERSEKUTUAN, MALAYSIA

Lesen untuk menggunakan Tanda Pensijilan di atas barangan
a licence to use the Certification Mark on
MEDICAL FACE MASKS

Please refer to detail in the SCHEDULE

sebagai mematuhi keperluan
as complying with
BS EN 14683 : 2019

Mohd Azanuddin bin Salleh
Ketua Pegawai Eksekutif
Chief Executive Officer
SIRIM QAS International Sdn. Bhd.

SIRIM QAS International Sdn. Bhd.
(No. Syarikat 410334-X)
1, Persiaran Dato' Menteri
Seksyen 2, Peti Surat 7035
40700 Shah Alam
Selangor Darul Ehsan
MALAYSIA.

Tel : 60-3-55446400
Faks : 60-3-55446466

http://www.sirim.my
http://www.malaysiancertified.com.my

Tarikh Mula Pensijilan : **23 December 2020**
Certified Since

Sah Sehingga : **23 December 2021**
Valid Until

Tarikh Dikeluarkan : **27 December 2020**
Issue Date

No Siri : 060408
Serial No

Lesen ini dianugerahkan tertakluk kepada syarat-syarat Perjanjian Pensijilan Barangan SIRIM QAS International Sdn. Bhd.
This Licence is granted subject to the provisions of the Product Certification Agreement of SIRIM QAS International Sdn. Bhd.

MADE IN MALAYSIA CERTIFICATE

Mask Certification

Why Made In Malaysia so important?

Ministry of Domestic Trade and Consumer Affairs (KPDNHEP) is responsible for processing application and issuing Made in Malaysia Logo marking to private or partnership businesses, private limited companies and cooperatives upon compliance with the requirements.

The Made in Malaysia Logo marking is an endorsement that the product is manufactured in Malaysia (country of origin).

No. Siri/ *Serial Number:* KPDNHEP/2020/LBM/00587-20232

KEMENTERIAN PERDAGANGAN DALAM NEGERI DAN HAL EHWAL PENGGUNA
MINISTRY OF DOMESTIC TRADE AND CONSUMER AFFAIRS

SIJIL PENGIKTIRAFAN
CERTIFICATE OF RECOGNITION

LOGO BUATAN MALAYSIA
MADE IN MALAYSIA LOGO

dengan ini memperakui bahawa
hereby certify that

1 SKU SEPERTI DI LAMPIRAN I

yang dikilangkan / dikeluarkan oleh:
manufactured by:

PECCA LEATHER SDN BHD
No. 1, Jalan Perindustrian Desa Aman 1A
Industri Desa Aman, Kepong
52200 Kuala Lumpur
Wilayah Persekutuan

telah memenuhi syarat-syarat bagi pensijilan Logo Buatan Malaysia
fulfill the terms and conditions for certification of Made in Malaysia Logo

Tempoh sah laku : 10 Disember 2020 – 10 Disember 2023
Validity : 10 December 2020 – 10 December 2023

Kementerian Perdagangan Dalam Negeri Dan Hal Ehwal Pengguna

KETUA SETIAUSAHA
KEMENTERIAN PERDAGANGAN DALAM NEGERI
DAN HAL EHWAL PENGGUNA

Tarikh / *Date :* 18 Disember 2020

BUATAN MALAYSIA
MADE IN MALAYSIA

RENTAS HEALTH SDN BHD (1322484-P)
No. 1 Jalan Perindustrian Desa Aman 1A, Industry Desa Aman, 52200 Kepong, Kuala Lumpur.

T: +603 6275 3800 **F: +603 6277 9809** **E: connect@rentashealth.com**

www.rentashealth.com rentashealth Rentas Health