RENTAS HEALTH

PECCA LEATHER

ADVANCING HEALTH TECH

STAY SAFE, STAY HEAL THY WITH RENT AS HEAL TH

MASK CERTIFICATION

ISO 13485 : 2016 CERTIFICATE

Mask Certification

Why ISO 13485 : 2016 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.

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

ISO 14001: 2015 CERTIFICATE

Mask Certification

Why ISO 14001:2015 so important?

ISO 14001 helps businesses of all sizes across all sectors make their day to day operations more sustainable. Sustainability can ultimately save money, improve brand reputation, engage employees and build resilience against uncertainty as well as the ability to rapidly adapt to change.

ISO 14001 Environmental Management System (EMS) enhance brand image as an eco-friendly company. Provides assurance of company's legal compliance. Facilitates access to the growing "green market". Cost-saving through the efficient use of resources and proper waste management.

CERTIFICATE

kiwa

Reg. Number	15919 - E	Valid From	2019-05-17
First issue date	2016-05-20	Last change date	2021-06-03
Valid until	2022-05-19	IAF Sector	22 , 14 , 05 , 04

Environmental Management System Certificate

ISO 14001:2015

We certify that the Environmental Systemof the Organization:

PECCA LEATHER SDN. BHD.

Is in compliance with the Standard UNI EN ISO 14001:2015 for the following products/services:

Manufacturing of leather and synthetic leather seat cover and interior finishing by laminating, cutting, sewing and related sub-processes. Design, development and manufacturing of face mask for surgical/ medical & general use, by slicing and ear loop welding.

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.
The date of issuance of this certificate is the date of first issue by another accredited body.
This certificateis composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39 051 459 3 111
Fax +39 051 763 382
Email: info@kiwacermet.it
www.kiwa.it

CERMET

PECCA LEATHER SDN. BHD.
Registered Headquarters
- No. 1, Jalan Perindustrian Desa Aman 1A, Industri Desa Aman, Kepong, 52200 Kuala Lumpur Malaysia

Certified sites
- No. 1, Jalan Perindustrian Desa Aman 1A, Industri Desa Aman, Kepong, 52200 Kuala Lumpur Malaysia

IAF

ACCREDIA

SGA N° 0100

ISO 45001: 2018 CERTIFICATE

Mask Certification

Why ISO 45001:2018 so important?

ISO 45001:2018 is designed to improve a company's OH&S performance in preventing injury and ill-health. This includes taking action to ensure that the job continues to be safe and healthy. Not only is it important to protect employees of workplace, but it is also imperative to improve health and safety performance.

CERTIFICATE

kiwa

Reg. Number	15919-I	Valid From	2019-11-04
First issuedate	2016-05-20	Last change date	2021-06-03
Valid Until	2022-11-03	IAF Sector	22 , 14 , 05, 04

Occupational Health and Safety Management System Certificate

ISO 45001:2018

We certify that the Occupational Health and Safety Management System of the Organization:

PECCA LEATHER SDN. BHD.

Is in compliance with the standard UNI ISO 45001:2018 for the following products/services:

Manufacturing of leather and synthetic leather seat cover and interior finishing by laminating, cutting, sewing and related sub-processes. Design, development and manufacturing of face mask for surgical/ medical & general use, by slicing and ear loop welding.

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.
This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)
Tel. +39 051 459 3.111
Fax +39 051 763.382
E-mail: info@kiwacermet.it
www.kiwa.it

CERMET

PECCA LEATHER SDN. BHD.
Registered Headquarters
- No. 1, Jalan Perindustrian Desa Aman 1A, Industri Desa Aman, Kepong, 52200 Kuala Lumpur Malaysia

Certified sites
- No. 1, Jalan Perindustrian Desa Aman 1A, Industri Desa Aman, Kepong, 52200 Kuala Lumpur Malaysia

IAF

ACCREDIA

SCR N° 013F

MDA CERTIFICATE

Establishment License

Why MDA so important?

For the purpose of placing a medical device in the market of 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.

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

Medical Device AUTHORITY MALAYSIA

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 : **MDA-1261-K120**
Licence No. :

Tarikh Sah Lesen : **24/08/2020 - 23/08/2023**
Licence Validity Date :

Lesen adalah dengan ini diberi kepada: **PECCA LEATHER SDN BHD**
Licence is hereby granted to:

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

Sebagai:
as:
PEMBUAT
MANUFACTURER

Orang yang bertanggungjawab:
Person Responsible:
MR KARUNAKARAN A/L KARUPPANNAN(I/C NO.: 661228-10-6198)

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

MADE IN MALAYSIA CERTIFICATE

Mask Certification

Why Made In Malaysia so important?

Ministry of Domestic Trade and Consumer AFairs (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 oforigin).

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

KETUA SETIAUSAHA
KEMENTERIAN PERDAGANGAN DALAM NEGERI
DAN HAL EHWAL PENGGUNA
Tarikh / *Date :* 18 Disember 2020

BUATAN MALAYSIA
MADE IN MALAYSIA

EU DECLARATION CE CERTIFICATION

Mask Certification

Why EU Declaration so important?

EU Declaration 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 EU Declaration of Conformity if they want to trade in EU/EAA markets.

Selling products without it, is an economic offence that is punished differently by each Member State of the European Union.

MDSS

Certificate of Verification

Medical Device Safety Service GmbH (MDSS)

hereby declares that an Authorized Representative's Mandate according to the EU Regulation 2017/745 (MDR) is in place and that the following tasks have been carried out in accordance with the requirements of the MDR on behalf of the Manufacturer:

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

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

MDSS complied with the registration obligations laid down in Article 123.3(d) and until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and/or 93/42/EEC have been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2021-08-10

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 467637

This certificate is subject to the following terms and conditions:
It is only valid for the device(s) listed hereafter;
It is not a proof for compliance to CE marking;
The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;
As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the MDR are fulfilled.
This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first.

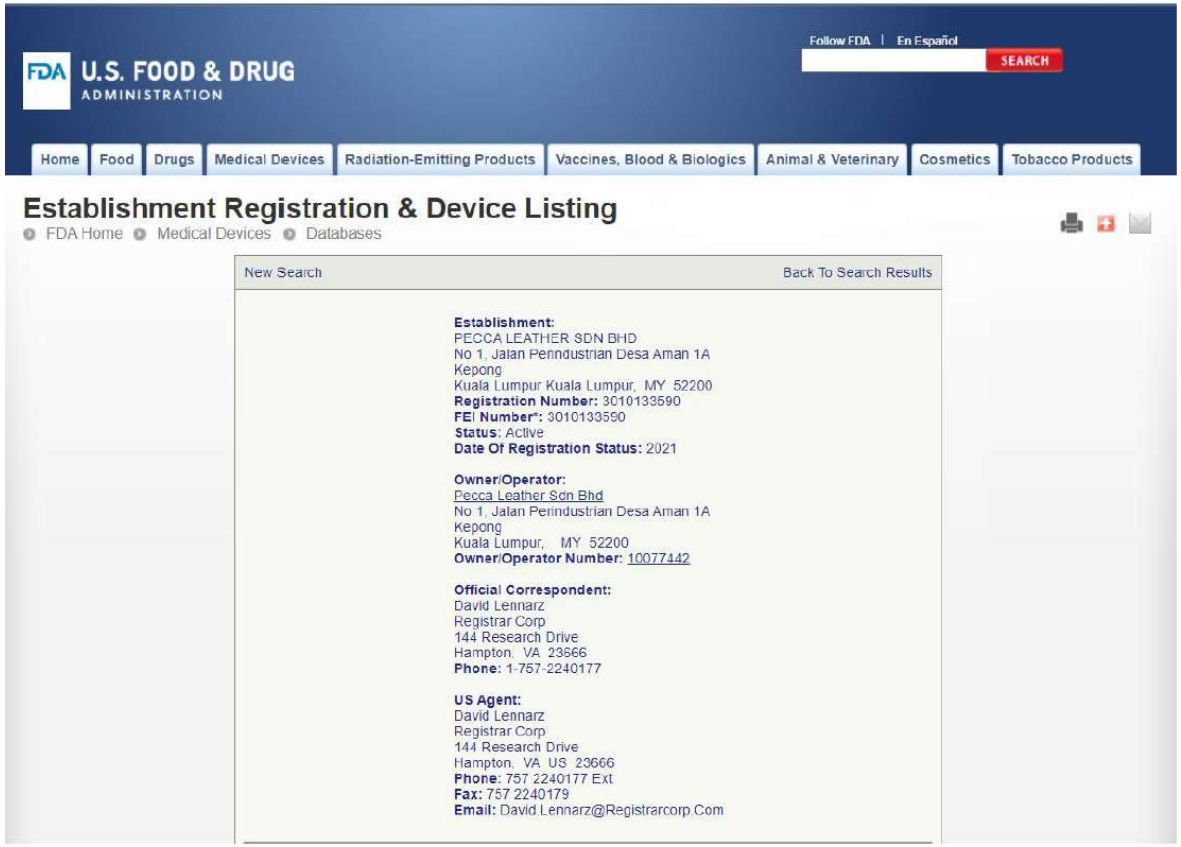
Page 1 of 2

FDA REGISTRATION

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

SIRIM CERTIFICATE
MEDICAL FACE MASK

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 14583 : 2019

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

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.

SIRIM CERTIFICATE
RESPIRATOR

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 : **PC010877**
Licence No :

LESEN PENSIJILAN BARANGAN
Product Certification Licence

SIRIM

PC 05102004 CB 01

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

RESPIRATORY PROTECTIVE DEVICES -FILTERING HALF MASKS

Please refer to detail in the SCHEDULE

sebagai mematuhi keperluan
as complying with

BS EN 149 : 2001+A1 : 2009

Nur Fadhilah binti Muhammad
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 : 60-3-55446456
http://www.sirim.my
http://www.malaysian-certified.my

Tarikh Mula Pensijilan : 18 March 2021
Certified Since

Sah Sehingga : 18 March 2022
Valid Until

Tarikh Dikeluarkan : 23 March 2021
Issue Date

No Siri : 062714
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.

CLEANROOM CERTIFICATE

Mask Certification

Why Cleanroom Certificate so important?

Cleanrooms are ideally suited for face mask manufacturer. Cleanrooms are enclosed and environmentally-controlled spaces in which temperature, humidity, pressure and contaminant levels are kept within strict limits. The controlled environment provided by a clean room helps to ensure that products remain under controlled contamination levels throughout the production process, thereby reducing potential risks to patients. Therefore, appropriate cleanroom designs, and the implementation of personnel policies and procedures that control work within the cleanroom environment, are critical for the production of safe devices.

Medical Devices Cleanrooms are clean air environments where a specific size of air particulates is prevented from entering. Cleanrooms keep air pollutants controlled during manufacturing and operations in face mask production. Our Medical Devices Modular Cleanrooms are developed to meet the required standard of the international organisation for standardisation (ISO) 14644-1: 2015.

NEXTECH

NEBB

CERTIFICATE OF COMPLIANCE

PECCA LEATHER SDN BHD

MASK PRODUCTION AREA

(ISO Class 8)

Test Condition: At Rest

As per requirement of ISO 14644 the designated area listed have met the respective acceptance criteria. Testing was performed as outlined in the above standard and the results are attested to it in the Report No: **292/CR-09/2021**

Nextech Sdn Bhd
NEBB
TAN CHEE KIAN
CERTIFICATION
3144
Exp. 3/31/22
Cleanroom Performance Testing

Date of Certification : 03/09/2021
Due Date : 03/09/2022

Tan Chee Kian
NEBB Certified Professional

NEXTECH SDN. BHD.
19, Jalan Bukit Bandung 26/4, HICOM Industrial Estate
40000 Shah Alam, Selangor Darul Ehsan, Malaysia.
Tel: 03-51923833 Fax: 03-51922088

FACE MASK PERFORMANCE

Callie offers a variety of masks designs, fit and filtration to match the protection needs for each procedure or risk level.

Material performance are tested and meet ASTM F2100 - 19 and EN 14683 :2019 requirement for surgical/medical face masks range. While respirator was tested and meets EN 149:2001+A1 :2009 & NIOSH 42 CFR part 84 standards.