



ADVANCING HEALTH TECH

STAY SAFE, STAY HEALTHY WITH RENTAS HEALTH

MASK CERTIFICATION

A close-up photograph of a hand holding a wooden stamp, poised to stamp a document. The stamp is a simple wooden block with a handle. Below it is a dark ink pad. The background is blurred, showing a desk with a blue folder and other items. The overall tone is professional and official.

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.



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 Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl
Via Cadriani, 23
40057 Granarolo dell'Emilia
(BO)
Tel +39 051 459.3.111
Fax +39 051 763.302
Email: info@kiwacermet.it
www.kiwa.it

CERMET



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 System of 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 certificate is composed of 1 page.

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



SGS RP 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.

			
Reg. Number	15919-I	Valid From	2019-11-04
First issued date	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
diagnostica e certificazione di
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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

SCR N° 0137

CERMET

MDA CERTIFICATE

Establishment License

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.

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 ESTABLISHMEN
ESTABLISHMENT LICENCE
Seksyen 15(1) Akta 737
Section 15(1) of Act 737

No. Lesen : **MDA-1261-K120** Tarikh Sah Lesen : **24/08/2020 - 23/08/2023**
Licence No. : 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 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).



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.



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 58, 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.

The screenshot shows the FDA's Establishment Registration & Device Listing page. The header includes the FDA logo and navigation links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. A search bar is located in the top right corner. The main content area displays the following information for the establishment:

Establishment:
PECCA LEATHER SDN BHD
No 1, Jalan Perindustrian Desa Aman 1A
Kepong
Kuala Lumpur Kuala Lumpur, MY 52200
Registration Number: 3010133590
FEI Number: 3010133590
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
[Pecca Leather Sdn Bhd](#)
No 1, Jalan Perindustrian Desa Aman 1A
Kepong
Kuala Lumpur, MY 52200
Owner/Operator Number: 10077442

Official Correspondent:
David Lennarz
Registrar Corp
144 Research Drive
Hampton, VA 23666
Phone: 1-757-2240177

US Agent:
David Lennarz
Registrar Corp
144 Research Drive
Hampton, VA US 23666
Phone: 757 2240177 Ext
Fax: 757 2240179
Email: David.Lennarz@Registrarcorp.Com

<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 : PC005383
Licence No :

LESEN PENSIJILAN BARANGAN
Product Certification Licence

 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 110294-B)
5, Persiaran Tropic Skypark
Bangsar 2, Post Box 1028
46200 Bukit Damansara
Selangor Darul Ehsan
03-55411554
Fax: 60-3-55496433
Email: info@sirimqas.com.my
http://www.sirimqas.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 S46 : 000406
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 95102094 CB 01


MEMBER OF INTERNATIONAL
COOPERATION AGREEMENT

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 410324-X)
1, Persiaran Dato' Merdiah
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.sirim.my/certification>

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.
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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.



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.

