CERTIFICATE

SIRIM QAS International Sdn. Bhd. hereby certifies that

KARANGKRAF MEDICARE SDN. BHD.
LOT 1, JALAN RENGGAM 15/5
OFF PERSIARAN SELANGOR
SEKSYEN 15
40200 SHAH ALAM
SELANGOR DARUL EHSAN
MALAYSIA

MDQMS 30092015 CB 04

has implemented a Quality Management System for Medical Devices complying with

ISO 13485 : 2016

Medical Devices - Quality Management System – Requirements For Regulatory Purposes (In Compliance with Act 737 and Medical Device Regulations 2012 requirements)

Scope of Certification

MANUFACTURING AND DISTRIBUTION OF MEDICAL FACE MASK.

RISK CLASSIFICATION OF MEDICAL DEVICE: CLASS A, RULE 4

Issue Date	:	**07 March 2021**
Original certification date	:	**07 March 2021**
Expiry Date	:	**06 March 2024**
Certification No.	:	**QMS-MD 00179**

SIRIM QAS INTERNATIONAL SDN. BHD.
(Co. No. 410334 - x)
1, Persiaran Dato' Menteri
Section 2, P.O. Box 7035
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NUR FADHILAH BINTI MUHAMMAD
Chief Executive Officer
SIRIM QAS International Sdn. Bhd.

This certificate is granted subject to the terms and conditions as stated in the Certification Agreement.

Test Results:

Product : **3 Ply Surgical Face Mask**
Brand : **Karangkraf**
Model : **IIR**
Size : **175mm x 95mm**

No.	Type of Tests	Requirements BS EN 14683:2019 Clause 5.2 and Table 1: Performance Requirements for Medical Face Masks	Results	Remarks
1.	Bacterial Filtration Efficiency* (BFE), % (BS EN 14683:2019 Clause 5.2.2 and Annex B) *No of tested specimens: 5*	Type I : ≥ 95 Type II : ≥ 98 Type IIR : ≥ 98	> 99.99	Pass
2.	Differential Pressure (Breathability), Pa/cm² (BS EN 14683:2019 Clause 5.2.3 and Annex C) *No of tested specimens: 5*	Type I : < 40 Type II : < 40 Type IIR : < 60	Average: 57.5	Pass
3.	Splash Resistance Pressure, kPa (BS EN 14683:2019 Clause 5.2.4 and ISO 22609: 2004) *No of tested specimens: 32*	Type I : Not required Type II : Not required Type IIR : ≥ 16.0	> 16.0 kPa (There was no sign of penetration, evidence of wetness or both appears on the viewing side of the total 32 specimens at 16.0kPa)	Pass
4.	Microbial Cleanliness*, cfu/g (BS EN 14683:2019 Clause 5.2.5) *No of tested specimens: 5*	Type I : ≤ 30 Type II : ≤ 30 Type IIR : ≤ 30	27	Pass

Note:

** Bacterial Filtration Efficiency (BFE) and Microbial Cleanliness test was conducted by SIRIM Industrial Biotechnology Research Centre (IBRC)*

SIRIM QAS International Sdn. Bhd. CHEMICAL & CONSUMER SECTION

Test Results:

Product : **3 Ply Surgical Face Mask**
Brand : **MediKraf**
Model : **IIR**
Size : **175mm x 95mm**

No.	Type of Tests	Requirements BS EN 14683:2019 Clause 5.2 and Table 1: Performance Requirements for Medical Face Masks	Results	Remarks
1.	Bacterial Filtration Efficiency* (BFE), % (BS EN 14683:2019 Clause 5.2.2 and Annex B) *No of tested specimens: 5*	Type I : ≥ 95 Type II : ≥ 98 Type IIR : ≥ 98	99.92	Pass
2.	Differential Pressure (Breathability), Pa/cm² (BS EN 14683:2019 Clause 5.2.3 and Annex C) *No of tested specimens: 5*	Type I : < 40 Type II : < 40 Type IIR : < 60	Average: 56.4	Pass
3.	Splash Resistance Pressure, kPa (BS EN 14683:2019 Clause 5.2.4 and ISO 22609: 2004) *No of tested specimens: 32*	Type I : Not required Type II : Not required Type IIR : ≥ 16.0	> 16.0 kPa (There was no sign of penetration, evidence of wetness or both appears on the viewing side of the total 32 specimens at 16.0kPa)	Pass
4.	Microbial Cleanliness*, cfu/g (BS EN 14683:2019 Clause 5.2.5) *No of tested specimens: 5*	Type I : ≤ 30 Type II : ≤ 30 Type IIR : ≤ 30	3	Pass

Note:

** Bacterial Filtration Efficiency (BFE) and Microbial Cleanliness test was conducted by SIRIM Industrial Biotechnology Research Centre (IBRC)*

SIRIM QAS International Sdn. Bhd. CHEMICAL CONSUMER SECTION

INDUSTRIAL BIOTECHNOLOGY RESEARCH CENTRE
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1, Persiaran Dato' Menteri, Section 2, P. O. Box 7035
40700 Shah Alam, Selangor Darul Ehsan, MALAYSIA
Tel: 603 - 5544 6953 / 6960 Fax: 603 - 5544 6988
Website: www.sirim.my

TEST REPORT

REPORT NO: R0051/21/B19/02	PAGE: 1 of 7

Applicant	:	Karangkraf Medicare Sdn Bhd, Lot 1, Jalan Renggam 15/5, Off Persiaran Selangor, Seksyen 15, 40200 Shah Alam, Selangor Darul Ehsan, Malaysia.
Manufacturer / Company	:	Same as above
Test Facility:	:	Industrial Biotechnology Research Centre (IBRC), Building 19, SIRIM Berhad.
Sample Name/ Trade Name:	:	3-Ply Surgical Face Mask Brand: Karangkraf
Reference Standard / Method of Test	:	ISO 10993-5: 2009. Biological evaluation of medical devices. Part 5: Tests for *in vitro* cytotoxicity. (LWI-238-02)
Description of Sample	:	Received one sample in good condition for testing with the following identification: 1. Brand : Karangkraf 2. Lot / Batch No: Not provided 3. Manufacturing Date : Not provided 4. Expiry Date : Not provided 5. Quantity received : 50 pieces 6. Size : 175 mm x 95 mm 7. Color : White 8. Storage : Room temperature
Date Received	:	12 January 2020
Job No.	:	J0051/21
Issue Date	:	01 FEB 2021

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TEST REPORT

REPORT NO: R0052/21/B19/57	PAGE: 1 of 14

Job No.	: J0052/21
Applicant:	: Karangkraf Medicare Sdn Bhd, Lot 1, Jalan Renggam 15/5, Off Persiaran Selangor, Seksyen 15, 40200 Shah Alam, Selangor.
Company	: Same as above
Sample Name	: 3-Ply Surgical Face Mask - Brand: Karangkraf
Test Name	: Primary Skin Irritation
Test Facility	: Industrial Biotechnology Research Centre (IBRC), Building 19, SIRIM Berhad.
Reference Standard	: ISO 10993-10 (E)-3rd Edition 2010-08-01 (Exclude clause 6.5: Human Skin Irritation Test) (LWI-238-57)
Receipt of Sample Date	: 12 January 2021
Experimental Start Date	: 17 January 2021
Experimental End Date	: 22 January 2021
Issue Date	: 25 January 2021