Certificate of Registration

This certificate of Registration certifies that:

KOMEMTEC Co., Ltd

177, Jeongicha 1-ro, Daema-myeon, Yeonggwang-gun,

Jeollanam-do, 57055, Republic of Korea

has registered with the US Food and Drug Administration pursuant to Title 21 of the United States Code of Federal Regulations.

Owner Operator Number: 10084340

Listed Device

QKR D401286 Face mask per Enforcement Policy

US Agent: Willow Glen Consultancy LLC

Willow Glen Number: WG2072071

Expiration Date: December 31, 2022

This certificate affirms that the above-named facility is registered with the US FDA pursuant to the regulations required by the US laws. This registration has been verified as effective by Willow Glen Consultancy as of the date below, unless such registration has been terminated after issuance of this Certificate. Willow Glen Consultancy makes no additional representations or warranties, nor does this certificate carry any to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Willow Glen Consultancy assumes no liability to any person or entity in connection with the foregoing, nor does the U.S. FDA recognize a certificate of registration issued by Willow Glen Consultancy.

Willow Glen Consultancy is a private agent not affiliated with the U.S. Food and Drug Administration.

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Date: February 11, 2022

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KOMEMTEC
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Yeonggwang-gun, Jeollanam-do
Republic of Korea

Muenster, 25.02.2022

Dermatological report on human Patch Test for primary skin irritation and to detect existing sensitisations of human subjects after single application of

KOMEMTEC 2D MASK

Customer:	KOMEMTEC 177, Jeonggicha 1-ro, Daema-myeon Yeonggwang-gun, Jeollanam-do Republic of Korea
Test Panel:	30 panellists of either sex, all with healthy skin
Concentration of the product:	undiluted

Management System ISO 9001:2015
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Amtsgericht Münster HRB 1348

Münsterländische Bank Thie & Co
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USt-ID: DE126040147 | DE92 3006 0601 0005 3901 50
BIC: MLBK DEH1MUE

PRINCIPLE AND METHODS

The objective of the study is to detect primary skin irritation potential and/ or existing allergic sensitisation to the test substance.

The product consists of different materials of which two are in direct skin contact:

1. inner layer

2. ear loop

The test substances are applied to the skin of the panellist via an occlusive patch at a suitable concentration.

The patch limits contact of the panellist's skin with the test substance to a local area and exposure is exaggerated due to the occlusive conditions. The skin is checked at 24, 48 and 72 hours.

The occlusion eases the absorption of the suspected topical allergen allowing it to penetrate the stratum corneum to the viable (effector) cells of the skin and thus presenting a local challenge to the immune system.

If the threshold level of sensitivity is reached, a positive reaction could potentially be induced.

A positive reaction to a correctly applied patch provides evidence of primary irritation to the substance tested, but is not necessarily evidence of sensitisation.

Patch testing provokes allergic skin reactions in already sensitised panellists.

PROCEDURES

Prospective panellists receive a complete explanation of study procedures. If they wish to participate and agree to the conditions of the study, panellists sign a written, informed consent and provide a medical history.

20 mg/ 20 µl of the undiluted test product is applied to an adhesive plaster (Curatest® F Folien-Testpflaster, Fa. Lohmann & Rauscher GmbH & Co. KG) and affixed to clinically healthy skin on the upper back. Textile products are affixed with a sample size of 0,8 cm Ø with the adhesive plaster on the upper back.

After a 24 hour exposure period, the plaster is removed and the exposed skin is dermatologically assessed and graded. The second and third assessments are performed after 48 and 72 hours respectively.

All assessments are conducted 30 minutes after removal of the test plaster.

Where a positive reaction is observed, but it is unclear whether the observed reaction is due to sensitisation or irritation, subsequent readings can be performed.

All assessments are performed under standard lighting conditions.

The panellists are instructed to keep the test sites dry.

PANELLISTS

The test panel included 30 adult male and female subjects.

This test group includes test persons with various skin types, such as: (very) dry, oily, mixed, normal and sensitive.

INCLUSION CRITERIA

- Subjects aged 18 years and above with healthy skin in the test area

EXCLUSION CRITERIA

- Acute diseases
- Pregnancy and lactation period
- Sensitisation to ingredients of the test plaster
- Severe illnesses
- Application of pharmaceutical products and skin care products with active ingredients until 4 weeks before testing
- Intake of drugs that possibly can interfere with skin reactions (steroids, antiallergics, topical immuno modulator, etc.)
- Extremely tanned skin

RESULTS

RESULTS OF PATCH TESTING FOR THE TEST SUBSTANCE

Results of patch testing for the component: inner layer

No.	Name	Gender	Age	Diagnosis	24 h	48 h	72 h
1.	GlLu	f	56	healthy skin	-	-	-
2.	HaEl	f	65	healthy skin	-	-	-
3.	HaLu	m	21	healthy skin	-	-	-
4.	HeLa	f	23	healthy skin	-	-	-
5.	HoLe	m	25	healthy skin	-	-	-
6.	KlSa	f	52	healthy skin	-	-	-
7.	LeAl	f	27	healthy skin	-	-	-
8.	LeHe	f	65	healthy skin	-	-	-
9.	LuJa	f	41	healthy skin	-	-	-
10.	MaVi	f	41	healthy skin	-	-	-
11.	MiAl	m	32	healthy skin	-	-	-
12.	OeAn	f	36	healthy skin	-	-	-
13.	OeKa	m	65	healthy skin	-	-	-
14.	OeMa	m	37	healthy skin	-	-	-
15.	OeUt	f	66	healthy skin	-	-	-
16.	OeNi	f	47	healthy skin	-	-	-
17.	PiMa	m	35	healthy skin	-	-	-
18.	ScSi	f	48	healthy skin	-	-	-
19.	ScTo	m	49	healthy skin	-	-	-
20.	ScBa	m	43	healthy skin	-	-	-
21.	ScSv	f	39	healthy skin	-	-	-
22.	ScAn	f	56	healthy skin	-	-	-
23.	ScDi	m	68	healthy skin	-	-	-
24.	SeJa	f	24	healthy skin	-	-	-
25.	SeMa	f	20	healthy skin	-	-	-
26.	StPa	m	29	healthy skin	-	-	-
27.	TöPa	f	25	healthy skin	-	-	-
28.	WeIn	m	49	healthy skin	-	-	-
29.	WeYv	f	45	healthy skin	-	-	-
30.	WiKi	f	55	healthy skin	-	-	-

RESULTS

RESULTS OF PATCH TESTING FOR THE TEST SUBSTANCE

Results of patch testing for the component: ear loop

No.	Name	Gender	Age	Diagnosis	24 h	48 h	72 h
1.	GlLu	f	56	healthy skin	-	-	-
2.	HaEl	f	65	healthy skin	-	-	-
3.	HaLu	m	21	healthy skin	-	-	-
4.	HeLa	f	23	healthy skin	-	-	-
5.	HoLe	m	25	healthy skin	-	-	-
6.	KlSa	f	52	healthy skin	-	-	-
7.	LeAl	f	27	healthy skin	-	-	-
8.	LeHe	f	65	healthy skin	-	-	-
9.	LuJa	f	41	healthy skin	-	-	-
10.	MaVi	f	41	healthy skin	-	-	-
11.	MiAl	m	32	healthy skin	-	-	-
12.	OeAn	f	36	healthy skin	-	-	-
13.	OeKa	m	65	healthy skin	-	-	-
14.	OeMa	m	37	healthy skin	-	-	-
15.	OeUt	f	66	healthy skin	-	-	-
16.	OeNi	f	47	healthy skin	-	-	-
17.	PiMa	m	35	healthy skin	-	-	-
18.	ScSi	f	48	healthy skin	-	-	-
19.	ScTo	m	49	healthy skin	-	-	-
20.	ScBa	m	43	healthy skin	-	-	-
21.	ScSv	f	39	healthy skin	-	-	-
22.	ScAn	f	56	healthy skin	-	-	-
23.	ScDi	m	68	healthy skin	-	-	-
24.	SeJa	f	24	healthy skin	-	-	-
25.	SeMa	f	20	healthy skin	-	-	-
26.	StPa	m	29	healthy skin	-	-	-
27.	TöPa	f	25	healthy skin	-	-	-
28.	WeIn	m	49	healthy skin	-	-	-
29.	WeYv	f	45	healthy skin	-	-	-
30.	WiKi	f	55	healthy skin	-	-	-

RESULTS

RESULTS OF PATCH TESTING FOR THE CONTROL
Results of patch testing for the control - blank patch test

No.	Name	Gender	Age	Diagnosis	24 h	48 h	72 h
1.	GlLu	f	56	healthy skin	-	-	-
2.	HaEl	f	65	healthy skin	-	-	-
3.	HaLu	m	21	healthy skin	-	-	-
4.	HeLa	f	23	healthy skin	-	-	-
5.	HoLe	m	25	healthy skin	-	-	-
6.	KlSa	f	52	healthy skin	-	-	-
7.	LeAl	f	27	healthy skin	-	-	-
8.	LeHe	f	65	healthy skin	-	-	-
9.	LuJa	f	41	healthy skin	-	-	-
10.	MaVi	f	41	healthy skin	-	-	-
11.	MiAl	m	32	healthy skin	-	-	-
12.	OeAn	f	36	healthy skin	-	-	-
13.	OeKa	m	65	healthy skin	-	-	-
14.	OeMa	m	37	healthy skin	-	-	-
15.	OeUt	f	66	healthy skin	-	-	-
16.	OeNi	f	47	healthy skin	-	-	-
17.	PiMa	m	35	healthy skin	-	-	-
18.	ScSi	f	48	healthy skin	-	-	-
19.	ScTo	m	49	healthy skin	-	-	-
20.	ScBa	m	43	healthy skin	-	-	-
21.	ScSv	f	39	healthy skin	-	-	-
22.	ScAn	f	56	healthy skin	-	-	-
23.	ScDi	m	68	healthy skin	-	-	-
24.	SeJa	f	24	healthy skin	-	-	-
25.	SeMa	f	20	healthy skin	-	-	-
26.	StPa	m	29	healthy skin	-	-	-
27.	TöPa	f	25	healthy skin	-	-	-
28.	WeIn	m	49	healthy skin	-	-	-
29.	WeYv	f	45	healthy skin	-	-	-
30.	WiKi	f	55	healthy skin	-	-	-

INTERPRETATION CRITERIA

The assessment is based on the morphologic changes detailed in the modified guidelines of ICDRG (Fregert S (1981/ 2nd edition) Manual of Contact Dermatitis. On behalf of the International Contact Dermatitis Research Group and the North American Contact Dermatitis Group, Munksgaard Publishers,Copenhagen).

Table 4: Grading of the patch test reactions

Symbol	**Morphology**	**Meaning**
-	no reaction	negative
?	only erythema, no infiltration	doubtful
+	erythema, infiltration, possibly discrete papules	weak positive reaction
++	erythema, infiltration, papules, vesicles	strong positive reaction
+++	erythema, infiltration, papules, confluent vesicles	extreme severe positive reaction
ir	different changes (soap effect, vesicles, bulla, necrosis)	irritative
nt		not tested

GENERAL DERMATOLOGICAL INTERPRETATION CRITERIA:

The distinction between irritation and allergy is of importance. As a general rule, a positive reaction is said to be „allergic“ if it has been graded as “+” to “+++ “ up to 72 hours or beyond.

Understanding the dynamics of the reaction may aid the assessment.

Allergic test reactions could persist ("Plateau-type”) or even worsen ("Crescendo-type") on the day after the plaster has been removed). A “Decrescendo”-type (decrease of reaction after removal of plaster) on the other hand, indicates irritation.

If delayed reactions only develop 10-14 days after application, (“iatrogenic”) sensitisation should be considered.

Irritative and allergic reactions present erythema and could also cause infiltration.

Papules, vesicles and bullae could demonstrate irritation as well as allergy, whereas pustules and necrosis point to severe irritation reactions.

Both reactions could spread beyond the original application site.

Moreover the individual expression of a reaction lies within a wide range.

CONCLUSION

No evidence of any skin disorder was detected in the test area of any of the 30 panellists after conducting patch testing for 24, 48 and 72 hours according to the internationally recognised guidelines of ICDRG (International Contact Dermatitis Research Group).

It can be concluded that the use of the product will not cause any unwanted skin reactions due to an irritating effect.

Dr. med. Gerrit Schlippe
Investigating specialist
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Literature:

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Republic of Korea

Muenster, 25.02.2022

Certificate

for the Product

KOMEMTEC 2D MASK

Dermatological test on humans in 2022

Study number: 2202088807

The dermatological test performed by us on your product under the control of dermatological specialists was passed for this product with the rating of

„excellent“

This product did not lead to toxic-irritative intolerance reactions in patch testing carried out in accordance with international guidelines. The preparation can therefore be declared as dermatologically tested.

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SZUTEST

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Onaylanmış Kuruluş/Notified Body 2195

EU TYPE EXAMINATION CERTIFICATE
AB TİP İNCELEME SERTİFİKASI

according to Regulation (EU) 2016/425 Personal Protective Equipment Annex V Module B
2016/425/AB Kişisel Koruyucu Donanım Yönetmeliği EK 5 Modül B

Certificate Number:
Sertifika Numarası: **2195 22 PPE 049**

Üreticinin Adı ve Adresi *Name and address of Manufacturer*	KOMEMTEC Co.,Ltd. 177, Jeongicha 1-ro, Daema-myeon, Yeonggwang-gun, Jeollanam-do, Republic of Korea
Üretim Adresi *Manufacturing Address*	Myeong Seong Apparel 23, Gongdan-ro 50beon-gil, Geumjeong-gu, Busan, Republic of Korea
Ürün Adı *Product Name*	Filtering Half Masks to Protect Against Particles
Ürün Tanımı *Product Description*	Filtering Half Masks to Protect Against Particles
Tip/Marka/Model/Sınıf *Type/Brand/Model/Class*	KOMEMTEC DURIFL MASK FFP2 NR (Medium & Large)
İlgili Standart(lar) *Related Standard(s)*	EN 149:2001+A1:2009
Ekipman Kategorisi *Category of Equipment*	Category III
Sertifika Dayanağı *Base of Certificate*	FR.PPE.10 Product Evaluation Form (PPE-B-049 / 26.04.2022)

SZUTEST Uygunluk Değerlendirme A.Ş, Notified body identification number 2195, certifies hereby conformity of the above mentioned product properties are in conformance with the essential requirements of Regulation (EU) 2016/425 of the European Parliament and the Council. The EU type examination has been carried out according to Annex V – module B of the Regulation. An integral part of the certificate is an inspection report containing examination findings and data on approved type identification. Validity of the certificate is conditioned by validity of normative documents stated in the Inspection Report. If the standards related to the certified products are amended or new standards issued it is necessary to check applicability of the certificate.
Without one of the modules C2 or D, this EU certificate is not sufficient to affix CE mark and Notified Body identification number 2195 to the products mentioned in the certificate.

2195 numaralı Onaylanmış Kuruluş, SZUTEST Uygunluk Değerlendirme A.Ş, yukarıda bahsi geçen ürünlerinlerin, 2016/425/AB Kişisel Koruyucu Donanım Yönetmeliği'nin temel gerekliliklerine uygunluğunu onaylar. AB Tip İncelemesi, Yönetmeliğin Ek 5 – Modül B'ye uygun olarak gerçekleştirilmiştir. Bu sertifikanın ayrılmaz parçası olan muayene raporu, inceleme bulgularını ve onaylanan tip tanımlamasını içerir. Sertifikanın geçerliliği, muayene raporunda belirtilen standartların ve bu yönetmeliğin geçerliliğine bağlıdır. Belgelendirilen ürünler ile ilgili standartlarda düzeltme yapılması veya yeni bir standard yayınlanması durumlarda, sertifikanın uygulanabilirliğinin kontrolü gereklidir. Bu AB sertifikası C2 veya D modüllerinden biri olmaksızın CE işareti ve 2195 onaylanmış kuruluş tanıtıcı numarasını, sertifikada belirtilen ürünlere iliştirmek için yeterli değildir.

Yayın Tarihi : 27/04/2022
Issue Date
Revizyon Tarihi : -
Revision Date
Geçerlilik Tarihi : 26/04/2027
Validity Date

Rukiye BALKAN
Genel Müdür Yardımcısı
Deputy General Manager

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according to Regulation (EU) 2016/425 Personal Protective Equipment Annex V Module B
2016/425/AB Kişisel Koruyucu Donanım Yönetmeliği EK 5 Modül B

Certificate Number:
Sertifika Numarası: **2195 22 PPE 049**

EK 1 / *ANNEX 1*

Tip/Model/Sınıf
Type/Model/Class : DURIFL MASK FFP2 NR (Medium & Large) – White

Test Raporu No – Tarih
Test Report No – Date : CT22-01949E – 11.04.2022

Teknik Dosya No – Tarih
Technical File No – Date : KMT2D-V01

Used Materials

Layers and Components	Material	Specification
1st Layer	Nonvowen Fabric – Spunbond	Colour.White Min. 99% Polypropylene 40±1,2 gsm
2nd Layer	Thin Film – POLYFLON PTFE	Colour: White 100% Polytetrafluoroethylene 32±1,2 gsm
3rd Layer	Nonvowen Fabric-Thermalbond JK	Colour: White 50% Polypropylene + 50% Polyethylene 38±1,2 gsm
Earloop	Knitted Elastic	Colour: White 75% Nylon + 25% Polyurethane Length: 18±2 cm
Nose Clip	Lapel	Colour: White 70% Polypropylene + 30% Iron Length: 10±2 cm

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Certificate Number:
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Ürün Fotoğrafları
***Product Pictures*:**

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