STATEMENT ON SVHC *Date:* 26.07.2019

PLAKENE PRODUCTS
REACH – SVHC

The European authorities continue to compile a provisional list (Candidate List) of Substances of Very High Concern (SVHC) which should be documented under the REACH Regulation, if present at a concentration greater than 0.1% in a chemical. A new list of Substances of Very High Concern has been published by ECHA on July 16th, 2019.

Melnik certifies that our Plakene products do not contain any of the substances mentioned on this Candidate List above the threshold concentration according to the last update (July 16th, 2019) of the Candidate List of the European Chemicals Agency (ECHA).

None of those substances are intentionally added into the masterbatch formulation.

Calaf, 26th July 2019

Production Manager

REACH - SVHC

La sociedad referente al producto " ":

Este certificado se emite en respuesta a su petició n respecto de si nuestros productos contienen Sustancias SVHC, según la regulación 1907/2006/EC (REACH).

Las sustancias SVHC están dirigidas a través del stemai de autorización (Reach Título VII). Las susta ncias SVHC se identifican a través de la "lista de candidatos" (referido en el artículo 59 del sistema de au torización) y gradualmente serán incluidas (Artículo 58) en AnexoXIV (sustancias sujetas a autorización) de la regu lación REACH.

Por la presente certificamos que hemos comprobado y obtenido los certificados correspondientes de nuestros proveedores de material prima de Polipropileno y demás componentes del producto "Film de Polipropileno", y que en base a estos certificados podemos garantizar que nuestros productos, fabricados por no contienen más de un 0,1% (w/w) de cualquier sustancia SVHC listadas en la lista de candidatas de la ECHA de acuerdo con el artículo 33 de la regulación REACH, según actualización del 2 de Mayo de 2018 (lista de productos químicos que pueden encontrar en el siguiente link de la ECHA: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp.

Sin embargo, puesto que nosotros no realizamos tests específicos para verificar la presencia potencial de SVHC en nuestros productos, nosotros no podemos garantizar que no hay ninguna traza de algún SVHC, como impurezas u otros, en nuestros productos.

Nuestro certificado no cubre:

- Cualquier modificación del producto garantizado por cualquier adición de otros productos en él
- Cualquier modificación perjudicial del producto gar antizado resultante del procesado del producto
- Cualquier uso inadecuado o almacenamiento del material y de los artículos finales.

El presente certificado es valido para un periodo de un año a partir de la fecha indicada.

Quedamos a su disposición para cualquier informació n adicional que puedan necesitar.

Calaf, 2 de Mayo del 2018

Responsable Fabricación

Test Report

Product:	disposable respirator MASK
Model /Type:	MK001
Trademark:	
Applicant:	
Address:	
Manufacturer	
Address:	
Laboratory:	Aerospace Testing Technology (Shenzhen) Co., Ltd.
Address:	3/F, Block A1, No. 5, 8th Road, Shapu Yangyong Industrial Park, Songgang Street,
Report Number	AST2003205039
Standard:	EN 14683:2019
Web :	http://www.ast-test.com

Tested By:_____ Date: *2020-04-01*

Approved By:_____ Date: *2020-04-01*

Aerospace Testing Technology (Shenzhen) Co., Ltd. AST.LAB Approved

航天检测技术（深圳）有限公司
广东省深圳市宝安区松岗街道沙浦洋涌工业区8路5号A1栋三楼
Aerospace Testing Technology (Shenzhen) Co., Ltd.
3/F, Block A1, No.5, 8th Road, Shapu Yangyong Industrial Park,
Songgang Street, Bao'an District, Shenzhen, Guangdong, China
Tel.（电话） ：0755-27781492
Fax.（传真） ：0755-27781492
Web.（网址） ：www.ast-test.com
E-mail(邮箱) ：ast@hangtianjc.com

TEST REPORT EN 14683:2019 Medical face masks —Requirements and test methods	
Report reference No.	AST2003205039
Test By	Megan
Approved By.	Thomas
Date of issue	2020-04-01
Date of test	2020-03-12 to 2020-04-01
Testing laboratory	Aerospace Testing Technology (Shenzhen) Co., Ltd.
Location	3/F, Block A1, No. 5, 8th Road, Shapu Yangyong Industrial Park, Songgang Street, Bao'an District, Shenzhen, Guangdong, China
Applican	
Address:	
Standards	EN 14683:2019
Procedure deviation	N/A
Non-standard test method	N/A
Type of test product	disposable respirator MASK
Trade mark.	N/A
Model/Type designation	MK001
TRF originator.	FHT
Copyright blank test report:	--
Test item particulars:	N/A
Test procedure	MDD Approval
Test Report Form No.	EN 14683

Possible test case verdicts :	
test case does not apply to the test object	N(/A.)
test object does meet the requirement	P(ass)
test object does not meet the requirement	F(ail)
General remarks:	
"(see remark #)" refers to a remark appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report a comma is used as the decimal separator. The test results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. Until otherwise specified, all tests are done under normal ambient condition 25℃±10℃, Max RH: 75% and air pressure of 860 mbar to 1060 mbar.	Attached with: Attachment - A. Photo Documentation
The test samples were pre-production samples without serial numbers. This report shall not be reproduced except in full without the written approval of the testing laboratory. This report covers MK001. The test result presented in this report relate only to the object tested. The samples tested comply with the requirements of this standard.	

EN 14683:2019			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
1	Scope		-
2	Normative references		-
3	Terms and definitions		-
3.1	aerosol gaseous suspension of solid and/or liquid particles		P
3.2	bacterial filtration efficiency (BFE) efficiency of the medical face mask material(s) as a barrier to bacterial penetration Note 1 to entry: The BFE test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials.		P
3.3	biocompatibility quality of being accepted in a specific living environment without adverse or unwanted side effects		P
3.4	cleanliness freedom from unwanted foreign matter		P
3.4.1	microbial cleanliness freedom from population of viable micro-organisms on a product and/or a package		P
3.5	colony forming unit (CFU) unit by which the culturable number of micro-organisms is expressed Note 1 to entry: The culturable number is the number of micro-organisms, single cells or aggregates, able to form colonies on a solid nutrient medium.		P
3.6	differential pressure air permeability of the mask, measured by determining the difference of pressure across the mask under specific conditions of air flow, temperature and humidity		P
3.7	filter material used for mechanical and physical separation or deposition of aerosol particles (liquid or solid) from the inhaled and exhaled air		N/A
3.8	infective agent micro-organism that has been shown to cause surgical wound infections or that might cause infection in the patient, members of staff or other		P
3.9	medical face mask medical device covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient		P
3.10	splash resistance ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure		NA

EN 14683:2019			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
3.11	surgical procedure surgical intervention penetrating skin or mucosa, performed by a surgical team under controlled environmental conditions		NA
4	Classification Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant.	Type II	P
5	Requirements		P
5.1	General		P
5.1.1	Materials and construction The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness	absence of particulate matter	P
5.1.2	Design The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours)	Metal strip fixing	P
5.2	Performance requirements		P
5.2.1	General All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.		P
5.2.2	Bacterial filtration efficiency (BFE) When tested in accordance with Annex B, the bacterial filtration efficiency (BFE) of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	Bacterial filtration efficiency (%), 98.9 %≥ 95 %	P
5.2.3	Breathability When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	Differential pressure (Pa/cm^2), 33.26 Pa/cm^2< 40 Pa/cm^2	P

EN 14683:2019			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
5.2.4	Splash resistance When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		N/A
5.2.5	Microbial cleanliness (Bioburden) When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested (see Table 1). NOTE EN ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation of the population of viable microorganisms on or in a medical device, component, raw material or package. To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below: The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.		N/A
5.2.6	Biocompatibility According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request. As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered.		P
6	Labelling and information to be supplied		P
	The following information shall be supplied in addition: a) number of this European Standard; b) type of mask (as indicated in Table 1).	EN 14683:2019 Type II	P
Annex A	Information for users		P
	When breathing, speaking, coughing, sneezing etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose. The majority of the nuclei are between 0,5 µm and 12 µm in diameter and especially the larger droplets can contain micro-organisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.		P
Annex B	Method for in-vitro determination of bacterial filtration efficiency (BFE)		P

Table 1-performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥95	≥98	≥98
Differential pressure(Pa/cm^2)	<40	<40	<60
Splash resistance pressure (kPa)	Not required	Not required	≥16,0
Microbial cleanliness (cfu/g)	≤30	≤30	≤30
[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements			

EC Declaration

Address

Description of product

disposable respirator MASK

Model(s)

MK001

Standards used, including number, title, issue date and other relative documents

EN 14683:2019

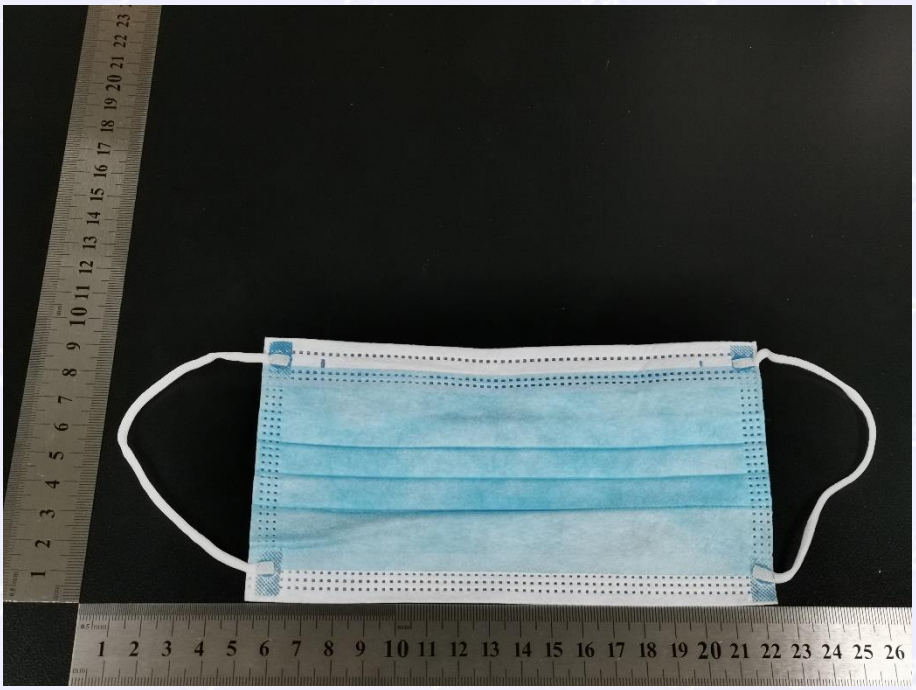
Declaration：

I declare that as the authorised representative, the above information in relation to the supply / manufacture of this product, is in conformity with the stated standards and other related documents following the provisions of the above Directives and their amendments.

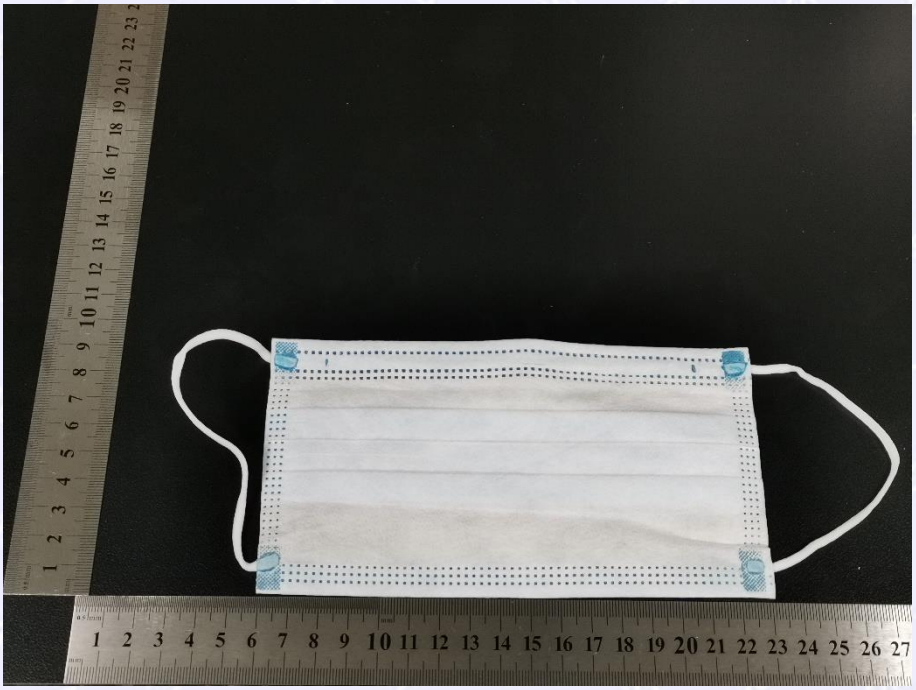
Signature Of Manufacturers Authorized:

2020. 04.01

Photo Documentation



1



2

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Test Photograph

1

2

End of Report

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DECLARATION OF COMPLIANCE

This Certificate confirms that the below mentioned packaging material was produced in accordance with the legal regulations under state of the art conditions of production following Regulation (EC) No. 2023/2006 on Good Manufacturing Practice.

This document is a Declaration of Compliance within the meaning of Article 16(1) of Regulation (EC) No 1935/2004 for “materials in contact with food”.

1. General Product Information

Date:	03.06.2015	Rev. Nr.	03
Producer:			
Customer:			
Customer Spec. Nr.:			
Spec. Nr.:	Code 032614		
Material description:	Paper 50 gr / PX 12 gr / Al 9 my / Extrusion Coating 25 gr		

Material description (from the outer to the inner layer):

Layer:	**based on**
Paper	Cellulose
Px	Low density polyethylene
AL	Aluminium
Extrusion coating (Layer in contact)	Ionomeric resin

Type of package/application: Packaging material for cosmetic products.

2. Compliance with General Legislation

The product named on this declaration complies with the applicable requirements of:

- EU “Framework” Regulation (EC) No. 1935/2004
- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.
- Regulation (EC) No. 2023/2006 on Good Manufacturing Practice.
- Directive 94/62/EC, Article 11 and US CONEG in respect to the heavy metal content of the sum of lead, cadmium, mercury and hexavalent chromium of < 100ppm.

2.1 Conditions of Use

The product is suitable for

☒ direct contact with food
☐ a suitable barrier between this material and the packed food is recommended

DECLARATION OF COMPLIANCE

2.2 Compliance with Overall Migration Limit (OML) of the Food Contact Layers

As laid out in Article 22 and 23 of the EU Regulation Nr. 10/2011 the test conditions for plastic materials and articles of Directive 82/711/EEC as amended remain valid in parallel with Annex V of EU Regulation Nr. 10/2011 during a transition period from 01/01/2013 until 31/12/2015. Article 20 of EU Regulation Nr. 10/2011 replaces the simulants in Directive 85/572/EEC as from 31/12/2012.

The product is in compliance with the OML of 10 mg/dm² following evaluation of relevant samples under following test conditions:

Simulants	Result	Units	Indic. Value	Limit of quant.
Migration (test conditions)	**10d 40ºC**			
10% ethanol	<1	**mg/dm²**	10	LOQ: 1
3% acetic acid	<1	**mg/dm²**	10	LOQ: 1
olive oil	<5	**mg/dm²**	10	LOQ: 5

LOQ: limit of quantification

For the evaluation an area volume ratio of 6 dm² / 1 kg food was taken into account.

The compliance refers only to migration compliance and not to technical fit-for-use.

3. Legal Compliance of the Layers

3.1 Paper

The paper fulfils the requirements of:

- Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact.
- Council of Europe Resolution AP(2002)1 on Paper and Board Materials and Articles intended to come into contact with foodstuffs.
- FDA Recommendations Title 21 CFR § 176.170 “Components of paper and paperboard in contact with aqueous and fatty foods” and § 176.180 “Components of paper and paperboard in contact with dry food”.
- BfR Recommendation XXXVI “Paper and board for food contact”.

3.2 PX

This grade complies with the requirements:

- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and amendments.
- FDA regulations Title 21 CFR § 177.1330 and 177.1520

DECLARATION OF COMPLIANCE

3.3 AL – Functional barrier

The aluminium foil fulfils the current recommendations and regulations:

- The used rolling oil complies with FDA, 21 CFR § 178.3910
- The chemical composition of our aluminium alloys are in accordance with the UNE EN 602 “Aluminium and aluminium alloys- Wrought products – Chemical composition of semi-products used for manufacturing articles intended to come into contact with food”.
- Aluminium foils > 6µm are regarded as a functional barrier.

3.4 Extrusion coating (Layer in contact)

This ionomer resin fulfils the current recommendations and regulations:

- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come in contact with food and amendments.
- FDA regulations Title 21 CFR 21 CFR § 177.1330

3.5 Compliance with Specific Restrictions

The used raw materials contain substances that have a restriction according to EU Regulation Nr. 10/2011 as amended.

The restricted substances listed in the following table may be present in the finished product:

CAS Nr. or PM-Ref Nr.	Substance	Restriction*
79-41-1	methacrylic acid	SML = 6 mg/kg
1314-13-2	zinc oxide	SML= 25 mg/kg (as zinc)

* restrictions can be a specific migration limit (SML), a maximum concentration (QM), a maximum quantity per surface area (QMA), or a ‘no detectable migration’ (ND) requirement at a certain detection limit (DL). Suffix (T) indicates a combined restriction for 2 or more substances.

The above list of restricted substances is complete to the extent that accurate information was received from our raw material suppliers.

The restrictions have beech checked by a 3rd party laboratory. They were proved not to be exceeded either by migration testing or by worst case calculation. For the evaluation an area/volume ratio of 6 dm^2/1kg food was taken into account

3.6 Dual Use Additives

As required by EU Regulation Nr. 10/2011 the following table identifies substances used as additives in plastics and subject to a restriction in food through an authorisation as food additive or flavouring (e.g. listed in Directive 89/107/EEC, Directive 88/388/EEC….).

DECLARATION OF COMPLIANCE

E Number	Substance
---	None

In absence of a Community reference list of these substances or a marking in Regulation Nr. 10/2011/EC this information received from our suppliers can only be considered as preliminary as we cannot exclude that the product may contain residual levels of some other dual use additives as introduced from raw materials for which we are currently not aware of.

4. Disclaimer

This declaration is given in good faith and to the best of our current knowledge. It describes the status of the products specified under General Product Information. The user of the product (or downstream user, if applicable) is responsible for ensuring that the finished package complies with applicable migration limits in the product itself under actual conditions of use.
Furthermore, the packer is responsible for verifying possible interactions of the products or its components with the products (e.g. modification of odour, taste, consistency, migration etc.) which are to be checked prior to use and in function of the end-uses and to ensure the general appropriateness of the packaging material for the intended use.

03/June/2015

Sofía Rodríguez
Quality Technician

FICHA TÉCNICA

COMPLEJO : **ESTUC. 1/C 50 GR/PX 12 GR/AL B 9 MY/SURLYN 25 GR** **COD. : 032614**	**EDICION :** 3 **FECHA :** 01/03/2004 **HOJA** 1 / 1

PROPIEDADES	METODO	UNIDAD	NOMINAL	TOLERANCIA
CARACTERÍSTICAS GENERALES :				
Papel	UNE-EN 536	g/m2	50	± 7%
Granzas Extrusion	UNE-EN 536	g/m2	12	± 10%
ALUMINIO	UNE-EN 536	g/m2	24	± 8%
		µ	9	
Granzas Extrusion	UNE-EN 536	g/m2	25	± 10%
GRAMAJE TOTAL	UNE-EN 536	g/m2	111	± 7%
CARACTERÍSTICAS MECANICAS :				
ADHESION	ASTM F-904	N/15 MM	3.50	MIN: 2.5
ALARG.TRANSV.	ASTM D-882	%	6	MIN: 4
ALARGAM.LONG.	ASTM D-882	%	2.50	MIN: 1.5
RES. SOLDADURA	ASTM F-88	N/15 MM	7	MIN: 6
RES.TRACCION LONG.	ASTM D-882	N/15 MM	75	MIN: 65
RES.TRACCION TRANSV.	ASTM D-882	N/15 MM	40	MIN: 30
CARACTERÍSTICAS FISICAS :				
PERMEAB. O2	ASTM D-3985	CC/M2.DIA		MAX: 0.05
PERMEAB. V.A.	ASTM F-1249	GR/M2.DIA		MAX: 0.05

El material deberá ser almacenado a una temperatura comprendida entre 10ºC y 30ºC

Antes de ser utilizado en máquina deberá acondicionarse, durante 24 horas, a la temperatura de la sala donde se vaya a procesar

Los datos reflejados en esta ficha, son el resultado de numerosos ensayos realizados en nuestros laboratorios.

Aconsejamos a nuestros clientes, contrastarlos en las condiciones efectivas de utilización del material.

papeles

CERTIFICATION OF COMPOSTABLE MATERIALS

The company:

SPAIN

Hereby certifies that the products:

PAPEL TOALLITA 41 GR.

Of the type:

Raw paper for wet wipe and industrial application

Is:

composition ***100% cellulose*** and ***Compostable material***

Director

1/10/2018