KBL 康龄医疗
MEDICAL SUPPLIES

KN95 Protective Mask

EN149:2001+A1:2009 FFP2 NR

KBL 康龄医疗
MEDICAL SUPPLIES

KN95 Protective Mask
Folding Mask

KBL 康龄医疗
MEDICAL SUPPLIES

KN95 Protective Mask
Folding Mask

KN95 Protective Mask
Folding Mask

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CERTIFICADO DE EXAMEN UE DE TIPO
EU-TYPE EXAMINATION CERTIFICATE

Notified Body No. 0370

ENAC CERTIFICACIÓN Nº 12/C-PR054

No. 0370-4301-PPE/B

ORGANISMO NOTIFICADO Nº *NOTIFIED BODY NUMBER*	**0370 - LGAI TECHNOLOGICAL CENTER** (APPLUS)
SOLICITANTE *APPLICANT*	**GuangZhou KangLing Medical Supplies Limited** ROOM 802 BUILDING1, MINGZHU AVENUE SOUTH NO.30, MINGZHU INDUSTRIAL PARK, CONGHUA DISTRICT GUANGZHOU
FABRICANTE *MANUFACTURER*	**GuangZhou KangLing Medical Supplies Limited** ROOM 802 BUILDING1, MINGZHU AVENUE SOUTH NO.30, MINGZHU INDUSTRIAL PARK, CONGHUA DISTRICT GUANGZHOU
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD / *APPLICABLE REGULATION TO GIVE CONFORMITY:* **REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL** *REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT*	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD *CONFORMITY ASSESSMENT PROCEDURE*	Módulo // *Module*: **B** **EXAMEN UE DE TIPO /** *EU TYPE EXAMINATION*
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) *IDENTIFICATION OF THE PPE (TYPE NUMBER)*	Ref.: KBL+100 PROTECTIVE MASK
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / *PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE*	FFP2 NR
NORMAS ARMONIZADAS / *HARMONISED STANDARDS*	EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado. *EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking*
FECHA DE EMISIÓN / *ISSUE DATE*	**02/09/2020**
VALIDEZ HASTA / *VALIDITY UNTIL*	**02/09/2025**

El presente certificado se mantendrá vigente durante 5 años siempre que el producto descrito no sea modificado y cumpla los requisitos esenciales de salud y seguridad establecidos en el Reglamento (UE) 2016/425. Para asegurar dicho cumplimiento, este certificado deberá ir acompañado de la documentación correspondiente a la Evaluación de Conformidad con el tipo según módulo C2, D (realizada por un Organismo Notificado, según frecuencia establecida).

This certificate will remain valid for 5 years as long as the indicated product is not modified and fulfills the essential requirements of health and safety established in (EU) Regulation 2016/425. To ensure such compliance, this certificate must be accompanied by the documentation corresponding to the Conformity Assessment to type according to C2, D(carried out by a Notified Body according, to the established frequency).

Applus LGAI Technological Center, S.A.

Xavier Ruiz Peña
Managing Director, Product Conformity B.U.

Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.
This document is not valid without its technical annex, whose number coincides with the number of certificate.

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ANEXO TÉCNICO
TECHNICAL ANNEX

0370-4301-PPE/B

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

MARCA *BRAND*	KangBaiLing
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) *IDENTIFICATION OF THE PPE (TYPE NUMBER)*	Ref.: KBL+100 PROTECTIVE MASK
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI *PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE*	FFP2 NR
INFORME DE ENSAYO *TEST REPORT*	PTC20072804601C-EN01V01 issued by Precise Testing & Certification (Guangdong) Co.,Ltd.(PTC)

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Organismo Notificado Nº 0370

CERTIFICADO DE CONFORMIDAD CON EL TIPO
CONFORMITY TO TYPE CERTIFICATE

CERTIFICACIÓN Nº 12/C-PR054

No. 0370-4594-PPE/C2

ORGANISMO NOTIFICADO Nº *NOTIFIED BODY NUMBER*	**0370 - LGAI TECHNOLOGICAL CENTER** (APPLUS)
SOLICITANTE *APPLICANT*	**GuangZhou KangLing Medical Supplies Limited** ROOM 802 BUILDING1, MINGZHU AVENUE SOUTH NO.30, MINGZHU INDUSTRIAL PARK, CONGHUA DISTRICT GUANGZHOU
FABRICANTE *MANUFACTURER*	**GuangZhou KangLing Medical Supplies Limited** ROOM 802 BUILDING1, MINGZHU AVENUE SOUTH NO.30, MINGZHU INDUSTRIAL PARK, CONGHUA DISTRICT GUANGZHOU
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD / *APPLICABLE REGULATION TO GIVE CONFORMITY:* **REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓ INDIVIDUAL** *REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT*	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD CON EL TIPO *CONFORMITY ASSESSMENT PROCEDURE TO TYPE*	Módulo // *Module*: **C2** **BASADA EN EL CONTROL INTERNO DE LA PRODUCCIÓN MÁS EL CONTROL SUPERVISADO DE LOS PRODUCTOS A INTERVALOS ALEATORIOS** *BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED CONTROL OF PRODUCTS AT ALEATORY INTERVALS*
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) *IDENTIFICATION OF THE PPE (TYPE NUMBER)*	Ref.: KBL+100 PROTECTIVE MASK
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / *PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE*	FFP2 NR
FECHA DE EMISIÓN / *ISSUE DATE*	**15/10/2020**
VALIDEZ HASTA / *VALIDITY UNTIL*:	**15/10/2021**
El presente certificado se mantendrá vigente durante 1 año siempre que no se modifiquen las condiciones establecidas en el Certificado de Examen UE de Tipo referenciado en el Anexo. *This certificate will remain in force for 1 year as long as the conditions established in the EU Type certificate referenced in the annex are not modified.*	

Applus® LGAI Technological Center, S.A.

Xavier Ruiz Peña
Managing Director, Product Conformity B.U.

Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.
This document is not valid without its technical annex, whose number coincides with the number of certificate.

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ANEXO TÉCNICO
TECHNICAL ANNEX

0370-4594-PPE/C2

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

Nº CERTIFICADO DE EXAMEN UE DE TIPO *NR. EU TYPE EXAMINATION CERTIFICATE*	**0370-4301-PPE/B**
EMITIDO POR *ISSUED BY*	LGAI TECHNOLOGICAL CENTER S.A. (APPLUS) **(Organismo notificado nº 0370 /** *Notified Body nr. 0370***).**
FECHA EMISIÓN *ISSUE DATE*	02/09/2020
VALIDEZ HASTA *VALIDITY UNTIL*	02/09/2025
MARCA *BRAND*	KangBaiLing
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) *IDENTIFICATION OF THE PPE (TYPE NUMBER)*	Ref.: KBL+100 PROTECTIVE MASK
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / *PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE*	FFP2 NR
INFORME DE ENSAYO DE CONFORMIDAD CON EL TIPO *CONFORMITY TO TYPE TEST REPORT*	PTC20091404801C-EN01 issued by Precise Testing & Certification (Guangdong) Co.,Ltd.(PTC).

Test Report No.: 178139791a 001

Client: **Guangzhou KangLing Medical Supplies Limited.**
Room 802, Building 1, Mingzhu Avenue South No 30, Mingzhu industrial Park, Conghua District Guangzhou China.

Contact Person: Minghao Niu

Sample Description As Declared :

No. Of Sample	:	90 Pcs
Product Description	:	KN95 Protective Mask
Colour	:	White
No.	:	KLM-4
Lot No./Batch code	:	20200420
Country of Origin	:	CHINA
Sales Destination(country)	:	Not Provided
Product End Use	:	Personal protection in non-medical environment
Test type	:	Partial test
Product type	:	Single shift use only
Claimed Classification	:	FFP2 NR

Sample obtaining method: Sending by customer

Sample Receiving date: 2020-04-28
Delivery condition: *Apparent good, Samples tested as received*
Test Period: 2020-05-06 to 2020-06-11

Test specification:	***Test result:***
Particulate respirator-half facepiece EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking^	Please refer to result page

For and on behalf of

TÜV Rheinland / CCIC (Qingdao) Co., Ltd.

2020-06-11 Alex Zhou / Senior Manager

Date *Name/Position*

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Material list

Material	Color	Location
Textile	White	White folding mask

Note:

	Shading shows the clauses requested
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "result details section for more information.
Fail	Requirement not satisfied. Refer to the "result details section for more information.
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

Result:

EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—Requirement, testing, marking.

7.4 **Package^** **NRq**

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

7.5 **Material^** **PASS [1]**

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Note 1: In accordance with the requirement.
Specimens -12,-29,-39 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.
Specimens -22,-35,-52 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.

7.6 **Cleaning and disinfecting^** **NAp [2]**

If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.

Note 2: Single shift use only.

7.7 **Practical performance^** **PASS** [3]

The particle filtering half mask shall undergo practical performance tests under realistic conditions

Note 3: No imperfections.

Specimen and subject details:

Specimen	Subject
-02	LCF
-28	TJ

7.8 **Finish of parts^**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. **PASS** [4]

Note 4: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

7.9.1 **Total inward leakage^** **PASS** [5]

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3;

And, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3.

Note 5: 48 out of the 50 individual exercise results were not greater than 11%; All of the 10 individual wearer arithmetic means were not greater than 8%. Detailed data are showed below.

Table 7.9.1-A Inward leakage test data

Test specification: EN149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head Up/down(%)	Talk(%)	Walk(%)	Mean(%)
TJ	-11	A.R.	4.3	7.7	11.0	8.3	6.1	7.5
CJW	-18	A.R.	1.8	4.0	4.7	0.8	3.2	2.9
SXW	-27	A.R.	3.1	7.1	8.3	8.3	5.7	6.5
LCF	-40	A.R.	1.6	4.5	10.6	4.7	1.2	4.5
GJB	-50	A.R.	6.2	8.6	6.3	13.3	2.3	7.4
ZH	-04	T.C.	2.3	1.4	5.9	11.0	4.0	4.9
TLX	-19	T.C.	6.8	7.8	9.3	3.9	1.1	5.8
TS	-34	T.C.	1.5	6.7	6.5	1.8	2.8	3.9
ZMM	-45	T.C.	6.7	7.6	11.2	7.0	2.0	6.9
YZF	-53	T.C.	4.6	3.2	3.8	2.0	4.2	3.6
Maximum permitted			**11**					**8**

Table 7.9.1-B Facial dimension

Subject	Face length(mm)	Face width(mm)	Face Depth(mm)	Mouth Width(mm)
TJ	105	151	110	52
CJW	114	147	101	65
SXW	110	147	117	57
LCF	119	165	121	56
GJB	109	154	109	57
ZH	102	152	113	55
TLX	104	153	112	40
TS	97	146	102	51
ZMM	114	157	119	50
YZF	113	151	106	48

7.9.2 **Penetration of filter material^** **PASS**

The penetration of the filter of the particle filtering half mask shall meet the requirements of below:

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	⩽ 20%	⩽ 20%
FFP 2	⩽ 6%	⩽ 6%
FFP 3	⩽ 1%	⩽ 1%

中国认可
国际互认
检测
TESTING
CNAS L5772

Test Report

EN 149:2001+A1:2009 protective devices. Filtering half masks to protect against particles. Requirements, testing, marking

Product:	PROTECTIVE MASK
Report No.:	PTC20072804601C-EN01
Client:	GuangZhou KangLing Medical Supplies Limited
Client Address:	ROOM 802 BUILDING1, MINGZHU AVENUE SOUTH NO.30, MINGZHU INDUSTRIAL PARK, CONGHUA DISTRICT GUANGZHOU
Manufacturer:	GuangZhou KangLing Medical Supplies Limited
Manufacturer Address:	ROOM 802 BUILDING1, MINGZHU AVENUE SOUTH NO.30, MINGZHU INDUSTRIAL PARK, CONGHUA DISTRICT GUANGZHOU
Contact:	Qing Wang
Model(s):	KBL+100
Classification:	FFP2 NR
Date of Tests:	Aug.01.2020～Aug.10.2020

Signed for and on Behalf of PTC

Prepare by: Checked by: Approved by:

Precise Testing & Certification (Guangdong) Co., Ltd. (PTC)
Building 1, No. 6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China.
Tel: 86-769-38808222 Fax: 86-769-38826111 http:// www.ptc-testing.com

Test Report

Summary of assessment

Clause	Assessment
7.3 Visual inspection	Not tested
7.4 Packaging	PASS
7.5 Material	PASS
7.6 Cleaning and disinfecting	N/A
7.7 Practical performance	PASS
7.8 Finish of parts	PASS
7.9.1 Total inward leakage	PASS
7.9.2 Penetration of filter material	PASS
7.10 Compatibility with skin	PASS
7.11 Flammability	PASS
7.12 Carbon dioxide content of the inhalation air	PASS
7.13 Head harness	PASS
7.14 Field of vision	PASS
7.15 Exhalation valve	N/A
7.16 Breathing resistance	PASS
7.17 Clogging	N/A
7.18 Demountable parts	PASS
9 Marking	Not tested

Remark:

PASS: comply with requirement of standard
N/A: not application
Not tested: the clause were not required

Test Report

Test Result:

Requirement	Test Result	Conclusion
7.3 Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer.	Not tested	**Not tested**
7.4 Packaging Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	In accordance with the requirement.	**Pass**
7.5 Material Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	No mechanical failure after undergoing the conditioning described in 8.3.1, No collapse when conditioned in accordance with 8.3.1 and 8.3.2.	**Pass**
7.6 Cleaning and disinfecting If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.	Single shift use only	**N/A**
7.7 Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions	No imperfections	**Pass**
7.8 Finish of parts Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs.	**Pass**

7.9.1 Total inward leakage

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1, 11 % for FFP2, 5 % for FFP3

and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1, 8 % for FFP2, 2 % for FFP3.

FFP2, Test results are shown in Annex A Table 7.9.1-A&B

Pass

7.9.2 Penetration of filter material

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤ 20%	≤ 20%
FFP2	≤ 6%	≤ 6%
FFP3	≤ 1%	≤ 1%

FFP2 , Test results are shown in Annex A Table 7.9.2.

Pass

7.10 Compatibility with skin

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

No irritation or any other adverse effect to health.

Pass

7.11 Flammability

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Test results are shown in Annex A Table 7.11.

Pass

7.12 Carbon dioxide content of the inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

Test results are shown in Annex A Table 7.12.

Pass

7.13 Head harness

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be

Head harness can be donned and removed easily, adjustable or self-adjusting and

Pass

Australian Government

Department of Health

Therapeutic Goods Administration

Record Summary	342072 Vicki Partridge Pty Ltd - Mask, surgical, single use
Sponsor	Vicki Partridge Pty Ltd
Therapeutic Type	Medical Device
Product Category	Included Class 1
ARTG Start Date	24/08/2020
Postal Address	46 The Peninsula, Paradise Point, QLD, 4216 Australia
Billing Address	46 The Peninsula, Paradise Point, QLD, 4216 Australia
Product Type	Medical Device - Class 1 - Included
Status	Active
Approval Area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address	Certificate number(s)
GuangzhoukangLing Medical Supplies Limited Company	30 AI-802 Mingzhu Street South Conghua District,Guangzhou City, China	

Products

1. Mask, surgical, single use

Product Type	Single Device Product	**Status**	Current
		Effective Date	24/08/2020

GMDN	35177 Mask, surgical, single use
Functional Description	Not included on record
Intended Purpose	A disposable device made from fabric placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms while surgery is being performed.

Variant Information

Device Information

10 Single-use devices

Specific Conditions

No Specific Conditions included on Record

Record Summary

Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Vicki Partridge Pty Ltd

for approval to supply

Vicki Partridge Pty Ltd - Public respirator, single-use

ARTG Identifier	342071
ARTG Start Date	24/08/2020
Product Category	Medical Device Included Class 1
GMDN	57793
GMDN Term	Public respirator, single-use
Intended Purpose	A form-shaped filtering mask designed to be placed over the nose and mouth protecting the wearer from large and small particles (e.g., bacteria and viruses). It is made of multiple layers of non-woven polymers to produce a soft, flexible mask that create an airtight seal against the user's face and secured using elastic ties. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
GuangzhoukangLing Medical Supplies Limited Company	30 AI-802 Mingzhu Street South Conghua District,Guangzhou City, China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

· - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Public respirator, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Bewertung der Konformität von Corona SARS-Cov-2 Pandemie Atemschutz (CPA) nach dem Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Revision 2
Evaluation of the conformity of corona sars-cov-2 pandemic respiratory protection (CPA) according to the testing principle for corona sars-cov-2 pandemic respiratory protection masks revision 2

Berichtsnummer *Report number*	3419098.10-CPA
Prüfgegenstand *Test subject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	Pandemie-Atemschutzmaske KBL-KN9501
Hersteller *Manufacturer*	Guangzhou Kangling medizinische Versorgung GmbH Raum 802, Gebäude 1, Mingzhu Südstraße Mingzhu Industriepark, Bezirk Conghua, Stadt Guangzhou, China
Importeur *Importer*	GuanZhou KangLing Medical Supplies Co., Ltd Room 802, Building 1, MingZhu Avenue South No. 30, Mingzhu Industrial Park, Conghua District, Guangzhou, China

Die Anforderungen des Prüfgrundsatzes sind:
The requirements of the test principle are:

erfüllt *fulfilled*	nicht erfüllt *not fulfilled*
✓	

Diese Bewertung bezieht sich auf die Ergebnisse der Prüfungen gemäß dem oben genannten Bericht. Die technische Wirksamkeit des oben genannten Produkts ist im Rahmen der Verkehrsfähigkeit gemäß § 9 Abs. 2 Medizinischer Bedarf Versorgungssicherstellungs-verordnung – MedBVSV zu vermuten. CPA mit Ausatemventil(en) eignen sich grundsätzlich nicht für den Fremdschutz.

This evaluation refers to the results of the assessments made in the above-mentioned report. The technical efficiency of the above-mentioned product is to be presumed within the framework of the marketability according to § 9 para. 2 Medical need supply-security-regulation – MedBVSV. CPA with exhalation valve(s) are generally not appropriate for external protection.

Dieses Verfahren ersetzt keine Konformitäts-bewertung nach der PSA Verordnung (EU) 2016/425. Die Bestätigung der Erfüllung aller Anforderungen des Prüfgrundsatzes alleine berechtigt auch nicht zur Bereitstellung entsprechender Produkte auf dem Unionsmarkt.

This procedure does not replace a conformity assessment according to the PPE Regulation (EU) 2016/425, nor does the confirmation of compliance with all requirements of the testing principle alone entitle the user to place corresponding products on the Union market.

Dieses Bewertungsschreiben dient für die Dauer der Feststellung der epidemischen Lage durch die Bundesregierung zur Vorlage bei den Marktaufsichtsbehörden zur Feststellung der Verkehrsfähigkeit. Dieses Schreiben darf nicht dazu genutzt werden um ein Produkt auf den Markt zu bringen. Die Verkehrsfähigkeit der PSA in der Bundesrepublik Deutschland stellt die zuständige Marktüberwachungsbehörde im Sinne des § 24 Absatz 1 Produktsicherheitsgesetz fest.

This letter serves for the duration of the determination of the epidemic situation by the Federal Government for submission to the market surveillance authorities for determination of marketability. This letter does not entitle to place a product on the market. The marketability of personal protective equipment in the Republic of Germany is determined by the responsible market surveillance authority in the sense of § 24 paragraph 1 of the Product Safety Regulations.

Sie können die für Sie zuständige Marktüberwachungsbehörde über die Website der ZLS suchen. Der Prüfgrundsatz kann ebenfalls über die Website der ZLS eingesehen werden.

You can find the market surveillance authority that is responsible for you on the website of the German ZLS. The test principle can also be found on the website of the German ZLS.

DEKRA Testing and Certification GmbH
Bochum, 2020-07-20

Jörg-Timm Kilisch
Geschäftsführer *Managing Director*

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle: Dinnendahlstraße 9, 44809 Bochum,
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

INFORME DE RESULTADOS DE ENSAYO

NYCE, LABORATORIOS, S. C.
ALFONSO HERRERA No. 15, COL. SAN RAFAEL, C.P. 06470, CIUDAD DE MEXICO
TEL. 55 5535 1882 CORREO-E: nycelab@nycelaboratorios.com

No. de Acreditación: MM-041-008/11, a partir de 2011-10-19 No. Aprobación: LPSTPS-036/14, a partir de 2014-03-18

No. de Informe: NL-DM-081833

DATOS DEL USUARIO

Nombre y/o Razón Social:	**SOCIEDAD GENERAL DE EVALUACIÓN SGE, S. A. de C. V.**				
Calle:	Lomas de Sotelo	**No. Ext.:**	1112	**No. Int. y/o Letra:**	201 y 202
Colonia o Poblado:	Lomas Hermosa		**Alcaldía o Municipio:**	Miguel Hidalgo	
Estado:	Ciudad de México		**Código Postal:**	11200	
Teléfono:		**Fax:**		**R. F. C.**	GES060906CC5

DESCRIPCIÓN DEL ELEMENTO DE PRUEBA

TIPO DE RESPIRADOR: RESPIRADOR DESECHABLE DE PRESIÓN NEGATIVA, LIBRE DE MANTENIMIENTO, N95 (3.1.10)

MARCA: KBL

MODELO: KBL+100

TALLA: UNITALLA

***CLASE:** N

****NIVEL DE EFICIENCIA DE FILTRADO:** 95 %

PAÍS DE ORIGEN: CHINA

COLOR: MATERIAL FILTRANTE BLANCO

*De acuerdo con la clasificación indicada en la propia norma numeral (4.2) **De acuerdo con la designación indicada en la propia norma numeral (4.3)

PRESENTA FILTRO ÚNICO [X] PAR [//]

OBSERVACIONES: RESPIRADOR DESECHABLE LIBRE DE MANTENIMIENTO, SIN VÁLVULA DE EXHALACIÓN

FECHA DE EMISIÓN DEL INFORME: 04 DE NOVIEMBRE DE 2020

EQUIPO UTILIZADO			
NOMBRE DEL EQUIPO	MARCA / MODELO	FECHA DE CALIBRACIÓN	FECHA DE VENCIMIENTO
CAMARA CLIMÁTICA	MARCA: ENVIROTRONICS MODELO: ENDH 1000/70	HUMEDAD RELATIVA 13 NOVIEMBRE 2019 TEMPERATURA 07 NOVIEMBRE 2019	HUMEDAD RELATIVA 13 NOVIEMBRE 2020 TEMPERATURA 07 NOVIEMBRE 2020
EQUIPO PROBADOR DE FILTROS	MARCA: TSI MODELO: 8130	05 DICIEMBRE 2019	05 DICIEMBRE 2020

ORIGINAL

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I ***COMPONENTES DEL RESPIRADOR (5.1):
***De acuerdo con la descripción u hoja técnica proporcionada por el fabricante.

a) PIEZA: FILTRO [//] BUCAL CON CLIP NASAL [X] CAPUCHA [//] CASCO [//]

b) FILTRO POLIPROPILENO

c) ARNÉS: BANDA PARA LA CABEZA

d) COMPONENTES OPCIONALES

a) EL RESPIRADOR TIENE VÁLVULA DE: EXHALACIÓN [NO] INHALACIÓN [NO]
b) EL RESPIRADOR TIENE TUBO DE RESPIRACIÓN [NO] [NO]

II ACABADOS DEL PRODUCTO (5.2):

PRESENTA:

FILOS: SI [//] NO [X]

ARISTAS SI [//] NO [X]

IMPERFECCIONES SI [//] NO [X] ¿Qué tipo?:

DEFECTOS SI [//] NO [X] ¿Qué tipo?:

III INSPECCIÓN VISUAL (5.3):
***De acuerdo con la descripción u hoja técnica proporcionada por el fabricante

A. FALTA ALGUNA PIEZA O COMPONENTE DEL RESPIRADOR SI [//] NO [X]
¿Cuáles?: _____.

B. PRESENTA VÁLVULAS SI [//] NO [X]

a) (en caso que sí) LA VÁLVULA PRESENTA DAÑO FÍSICO SI [//] NO [//]
b) (en caso que sí) LA VÁLVULA PRESENTA DEFORMACIONES SI [//] NO [//]
a) IMPIDE SU AJUSTE CON EL FILTRO SI [//] NO [//]

C. PRESENTA: ARNÉS [//] BANDA PARA LA CABEZA [X]
Materiales de las bandas para la cabeza: material elástico sintético recubierto con hilo de poliéster

a) PRESENTA DEFORMACIONES SI [//] NO [X]
b) LAS DEFORMACIONES IMPIDEN SU CORRECTA COLOCACIÓN SI [//] NO [X]
c) IMPIDE SU AJUSTE CON EL FILTRO SI [//] NO [X]

D. PRESENTA: FISURAS [NO] RASGADURAS [NO]

a) (en caso que sí) EN LA PIEZA FACIAL [//] EN EL FILTRO [//]

IV ARNESES PARA LA CABEZA (5.4):
***De acuerdo con la descripción u hoja técnica proporcionada por el fabricante.

A. ***PARA LA PIEZA FACIAL (EXCEPTO LOS RESPIRADORES LIBRES DE MANTENIMIENTO),
ES AJUSTABLE SI [//] NO [//]
ES REEMPLAZABLE SI [//] NO [//]

B. ***PARA LA PIEZA BUCAL,
EL ARNÉS ES AJUSTABLE SI [//] NO [//]
EL ARNÉS SOSTIENE LA PIEZA BUCAL EN SU LUGAR SI [//] NO [//]

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RESULTADOS DE PRUEBA

6.1.3.3 ACONDICIONAMIENTO DE LAS MUESTRAS:

Humedad Relativa: 85 % ± 5 % Temperatura: 38 °C ± 2.5 °C Tiempo: 25 h ± 1 h

TAMAÑO DE LA MUESTRA A ENSAYAR: 10 piezas (2 prueba de carga, 8 pruebas puntuales)

6.1.4.3 PRUEBA DE CARGA

(DETERMINACIÓN DE LA CONCENTRACIÓN GRAVIMÉTRICA Y DEL TIEMPO DE PRUEBA)

FILTRO (FIBRA DE VIDRIO)	TIEMPO DE LA PRUEBA	FLUJO	PESO FINAL DEL FILTRO	PESO INICIAL DEL FILTRO	PESO NETO DEL AEROSOL
GELMAN	(min)	(L/min)	(mg)	(mg)	(mg)
	12	85	582.5	556.1	26.4

(DETERMINACIÓN DEL TIEMPO DE PRUEBA)

CLASE	NIVEL DE EFICIENCIA	CONCENTRACIÓN GRAVIMÉTRICA CALCULADA $\dot{C}$ (mg/m³)	NIVEL OBJETIVO DE EXPOSICIÓN AEROSOL E (mg)	FLUJO Q (L/min)	TIEMPO DE PRUEBA CALCULADO t (min)
N	95 %	25.9	200	85	90.9

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6.1 RESISTENCIA A LA PENETRACIÓN
6.2 RESISTENCIA AL FLUJO DE AIRE

FILTRO	CLASE	NIVEL DE EFICIENCIA	TIEMPO DE PRUEBA	FLUJO	PENETRACIÓN	EFICIENCIA DEL RESPIRADOR	RESISTENCIA AL FLUJO DE AIRE		
							(ΔP_F)	(ΔP_H)	($\Delta P_F - \Delta P_H$)
#			(s)	(L/min)	(%)	(%)	(mm H_2O)	(mm H_2O)	(mm H_2O)
1	N	95 %	10.30	84.6	0.004	99.996	17.0	0.4	16.6
2			10.40	84.7	0.002	99.998	16.8	0.3	16.5
3			10.50	84.8	0.003	99.997	16.9	0.4	16.5
4			10.40	84.8	0.000	100.00	17.4	0.4	17.0
5			10.50	84.8	0.000	100.00	16.9	0.4	16.5
6			10.40	84.9	0.003	99.997	17.1	0.4	16.7
7			10.40	84.8	0.000	100.00	17.1	0.3	16.8
8			10.40	84.8	0.000	100.00	16.8	0.4	16.4

ΔP_F = Caída de presión al inicio de la prueba ΔP_H = Caída de presión del sistema de prueba

7.1.1 MARCADO EN EL PRODUCTO:

a) **NOMBRE O RAZÓN SOCIAL Y/O MARCA REGISTRADA DEL FABRICANTE, COMERCIALIZADOR O IMPORTADOR: KBL**
b) **MODELO O DENOMINACIÓN DEL FILTRO: KBL+100**
c) **DESIGNACIÓN DE ACUERDO CON SU TIPO Y NIVEL DE EFICIENCIA DEL FILTRADO: NO PRESENTA**
d) **CONTRASEÑA OFICIAL DE CUMPLIMIENTO CON LA NORMA NOM-116-STPS-2009: NO PRESENTA**

INFORME DE RESULTADOS DE ENSAYO

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PRUEBAS REALIZADAS CONFORME A LA NORMA OFICIAL MEXICANA:

NOM-116-STPS-2009 "SEGURIDAD-EQUIPO DE PROTECCIÓN PERSONAL-RESPIRADORES PURIFICADORES DE AIRE DE PRESIÓN NEGATIVA CONTRA PARTÍCULAS NOCIVAS-ESPECIFICACIONES Y MÉTODOS DE PRUEBA"

OBSERVACIONES
Sello NYCE 29365 6DVS Prueba de carga Tiempo calculado 90.9 minutos Se realizaron 2 pruebas de carga Este informe consta de 5 páginas, 2 gráficas de prueba de carga, una hoja de muestreo y dos hojas oficio de alta en la STPS.

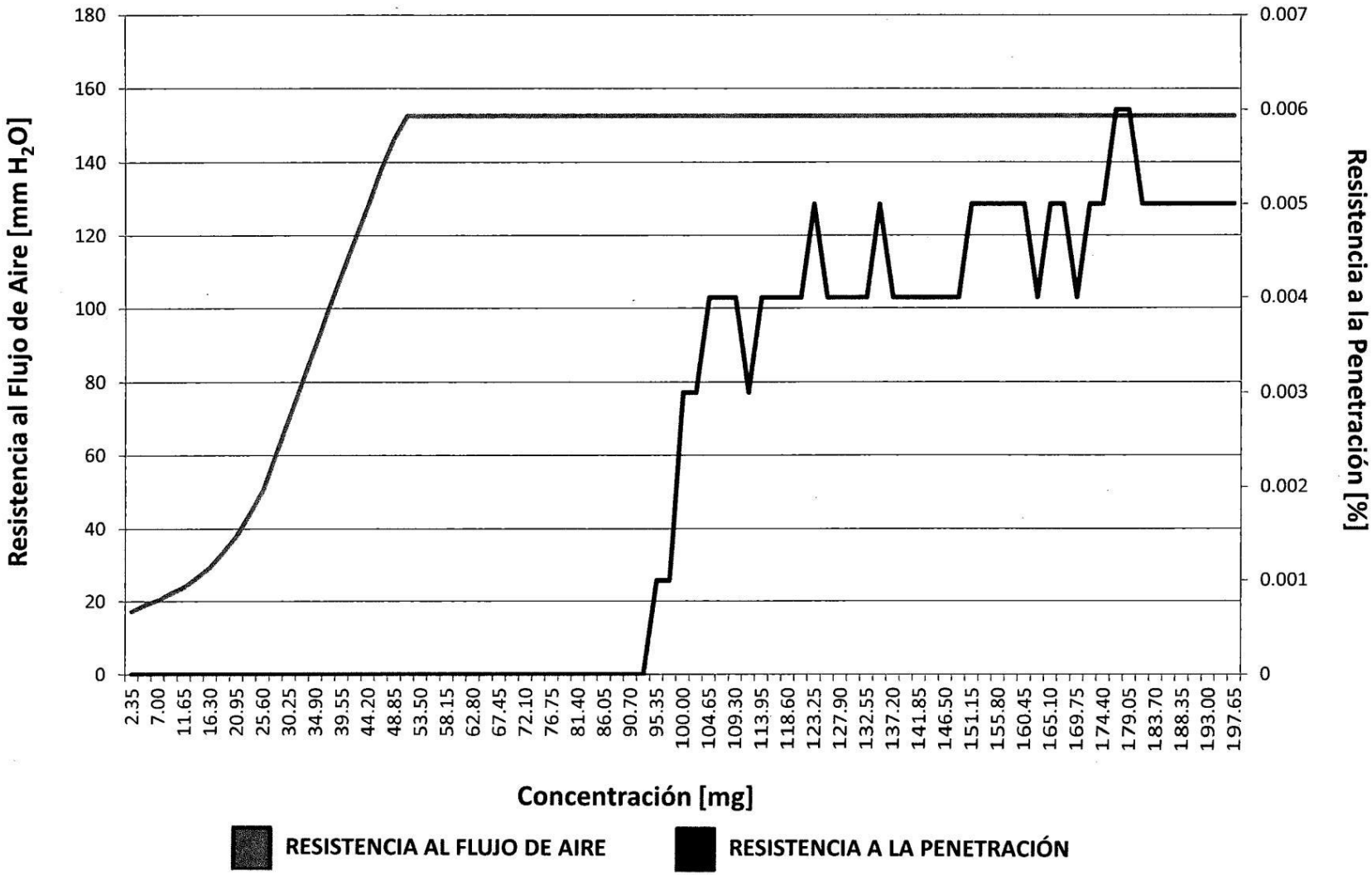
FECHAS		
Recepción	**Inicio**	**Fin**
26 de octubre de 2020	**28 de octubre de 2020**	**29 de octubre de 2020**

Ing. Martín LOZANO PALOMARES
Líder de Desarrollo de Proyectos

Fin del Informe de
Resultados de Ensayo

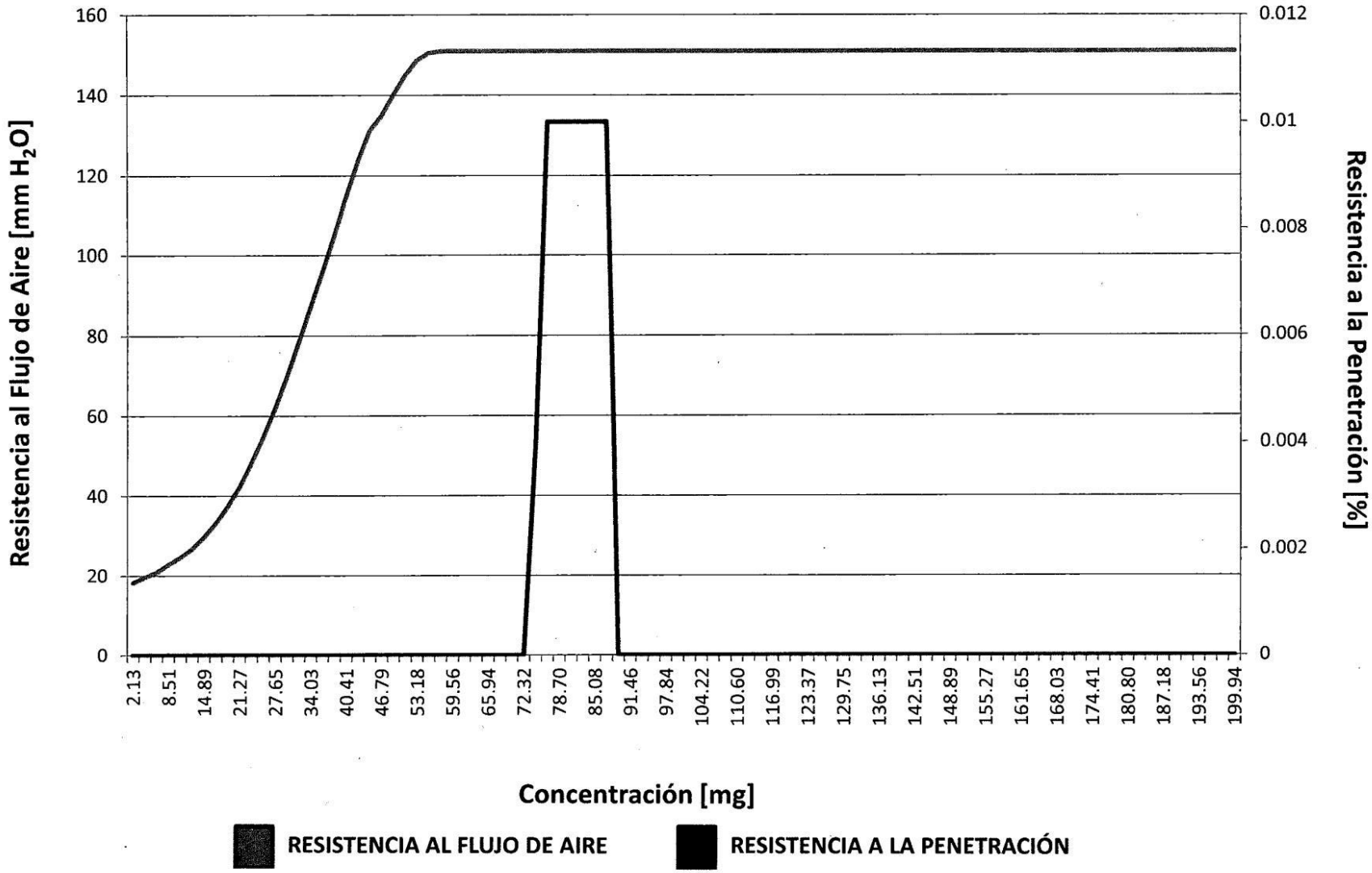
NYCE
LABORATORIOS

PRUEBA DE CARGA
RESISTENCIA AL FLUJO DE AIRE / RESISTENCIA A LA PENETRACIÓN
RESPIRADOR
MUESTRA 1
O de T: 081833



NYCE
LABORATORIOS

PRUEBA DE CARGA
RESISTENCIA AL FLUJO DE AIRE / RESISTENCIA A LA PENETRACIÓN
RESPIRADOR
MUESTRA 2
O de T: 081833



ANEXO

RECEPCIÓN DE MUESTRAS POR EL LABORATORIO

FR4PGS1A

DATOS QUE DEBEN INDICAR LOS SELLOS, CINTAS Y ETIQUETAS UTILIZADAS EN LAS VISITAS DE SEGUIMIENTO DE NYCE.

NÚMERO DE ETIQUETAS UTILIZADAS: UNA

FOLIO DE LAS ETIQUETAS UTILIZADAS: 29365

ESTADO FÍSICO DE LAS ETIQUETAS: EN BUEN ESTADO

ESTADO FÍSICO DE LA CINTA: EN BUEN ESTADO

ESTADO FÍSICO DE LA MUESTRA: EN BUEN ESTADO

SIGLAS Y NUMERO QUE PRESENTA EL SELLO DE LA PERSONA QUE REALIZO LA VISITA DE SEGUIMIENTO 6PDVS
(LA ETIQUETA PUEDE PRESENTAR DVS, MDS, GDS, TDS)

ETIQUETA CON BASE EN LA NOM-017-SCFI (EN SU CASO): -----

Nota: Este formato deberá ser llenado por cada muestra que sea presentada al laboratorio de pruebas.

En caso de instrumentos de medición (de masas) electrónicos será necesario que una copia de este anexo, el laboratorio de calibración lo adjunte al producto para conocimiento del laboratorio de pruebas de la NOM-001-SCFI, vigente. Este laboratorio a su vez lo anexará a su informe.