KATALOG 12 -24 11 2020 - -

FFP2 :

Polipropylenu BFE 95% -

- norma GB2626 -2006

EN 149:2001+A1:2009 – PPE)

MANUFACTURE : Shenzhen meili medical devices Ltd.

The manufacture sales as one of the integrated enterprises, We have 8 years of production experience, workshop area of 5000 square meters, with 200 employees, 200 sets of professional mask equipment, 60 million face mask are produced every year.

We currently have the qualifications of labor protection masks and medical masks, FDA certification. We mainly produce FFP2 masks and disposable medical masks, medical protective masks, labor protective masks, have multiple production lines and complete Service team, Welcome to order!

Standardy KN95. 5vrstvá maska na obličej

- ✓ Jednorázová maska FFP2: hygienická a pohodlná k použití.
- ✓ Vícevrstvá a prémiová kvalita: Vnitřní hydrofilní vrstva + filtrační vrstva + hydrofobní vrstva.
- ✓ Vyrobeno z vysoce kvalitního materiálu, bezpečné, měkké a pohodlné.
- ✓ Zabraňte kapičkám a 95% filtraci: Pokrytím úst a nosu zabraňuje šíření kapiček. Jednoduché kroky při nošení.
- ✓ Účinně vás ochrání před nakažením virem, zvláště když jste venku.
- ✓ Jednotná velikost: Elastické pásky a nastavitelná spona na nos pro různé tvary a velikosti obličeje.
- ✓ Široké použití: Domácí i profesionální použití, ideální pro každodenní použití, venkovní aktivity a nemocnice.

Výrobky se vyrábí podle čínského standardu GB2626-2006 a poskytuje komplexní bezpečnostní inspekční zprávy a certifikáty o kvalifikaci produktu.

Ověření: Standard: EN 149:2001 + A1:2009


FFP2
PROTECTIVE MASK
FFP2
CE | PROTECTIVE MASK
EN 149:2001+A1:2009
FFP2 PROTECTIVE MASK
10
KUSŮ
NÁVOD NA POUŽITÍ
2025-06
FFP2 PROTECTIVE MASK

NÁVOD NA POUŽITÍ

Manufacturer:
Shenzhen Meili Medical Devices Co., Ltd.
301Room 301, No. 33, 7Rix Road,
East District of Business Community,
Fuyong Street, Bao'an District, Shenzen City

datum expirace / expiry date
2025-06

2163

FFP2
PROTECTIVE MASK

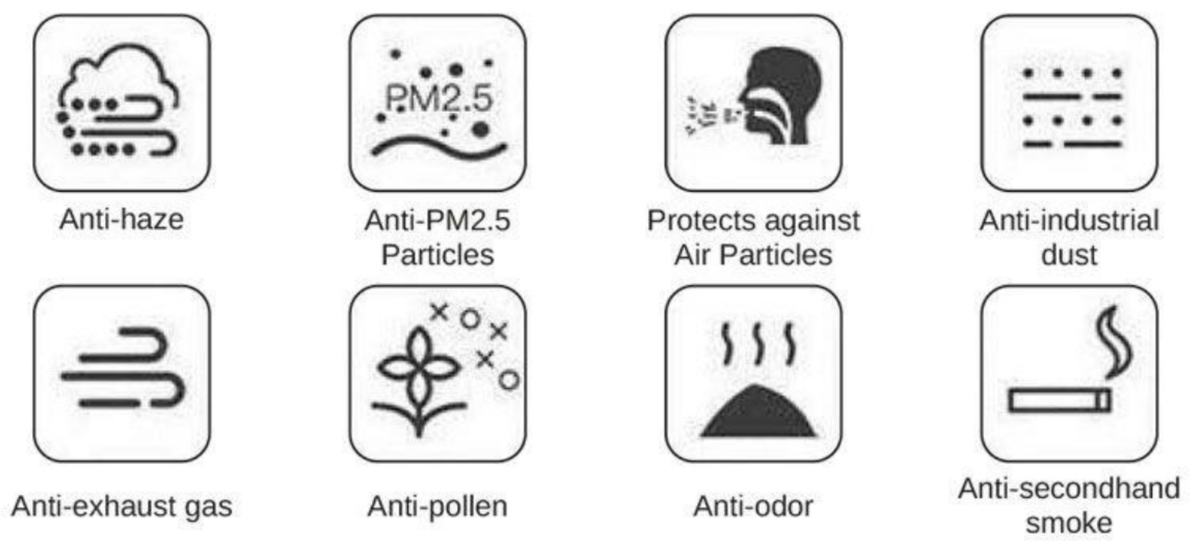
FFP2
CE | PROTECTIVE MASK
EN 149:2001+A1:2009

10
KUSŮ

FFP2 PROTECTIVE MASK

FFP2 PROTECTIVE MASK


5 LAYERS OF EFFICIENT PROTECTION
Layer-by-layer filtering gives breath more safety protection
Can effectively filter germs, dust, haze
01
NON-WOVEN
Filter large particles
02
MELTBLOWN CLOTH
Stops 94% of viruses
03
ANTIBACTERIAL NON-WOVEN FABRIC
Filters P2.5 particulate bacteria
04
NON-WOVEN LAYER
Enhanced filtration of fine particles
05
SKIN-FRIENDLY NON-WOVEN LAYER
Soft and skin-friendly
95%
FILTERING EFFECT


PM2.5
Anti-haze
Anti-PM2.5 Particles
Protects against Air Particles
Anti-industrial dust
Anti-exhaust gas
Anti-pollen
Anti-odor
Anti-secondhand smoke

Anwendungsanleitung.

Lände vor dem Anlegen und nach dem Abnehmen gründlich waschen.
Halten Sie die Maske an den Bändern so, dass der Nasenbügel nach oben zeigt und biegen Sie ihn gerade. Drehen Sie die Maske so, dass Sie in den nach innen gewölbten Teil schauen können. Nehmen Sie die Maske an den Bändern und platzieren Sie sie über die Ohren, Mund und Nase. Berührungen der äußeren und inneren Maskenfläche möglichst vermeiden. Passen Sie den Nasenbügel der Maske mit der Hand dem Nasenrücken an. Platzieren Sie diese am Kinn, sodass sie bequem sitzt. Testen Sie den korrekten Sitz: Beim Einatmen dürfen keine Luftströme am Mas- kenrand wahrnehmbar sein. Korrigieren Sie den Sitz wenn notwendig. Sollte ein dichtes Anliegen der Maske nicht erreichbar sein, darf der Bereich, in dem eine Atemschutzmaske getragen werden muss, nicht betretenwerden.

NÁVOD K POUŽITÍ

1. Rozbalte respirátor tažením horního a spodního panelu oběma rukama, aby vznikl mušlový tvar
2. Nasaďte si masku na obličej tak, aby zakrývala ústa a nos. Pásky přetáhněte za uši, tak aby Vám maska dobře držela na obličeji.
3. Přitiskněte a upravte masku k obličeji tak, aby byla zajištěna těsnost.
4. Rouška je správně a pěvně připevněna, pokud cítíte silný odpor proti výdechu a stěny masky se tisknout pryč od obličeje.

Certificate Number: HW20200322014S
Personal Protective Equipment Regulation
(EU) 2016/425

Certificate Of Compliance

Applicant	:	Shenzhen Meili Medical Devices Co., Ltd Room 301, No. 33, Rifu Road, East District of Baishixia
Address	:	Community, Fuyong Street, Bao'an District, Shenzhen City, China
Manufacturer	:	Shenzhen Meili Medical Devices Co., Ltd Room 301, No. 33, Rifu Road, East District of Baishixia
Address	:	Community, Fuyong Street, Bao'an District, Shenzhen City, China
Product	:	Disposable protective mask
Model	:	17.5*9.5cm-3P, Lug type 17.5*9.5cm-3p

The submitted products have been tested by us with the following standard(s) and found to be in compliance with the listed European Directives.

EN 149: 2001+A1:2009

The test results apply only to the particular sample tested and to the specific tests carried out. Technical Report and documentation are at the Holder's disposal.
This certificate applies specifically to the sample investigated in our test reference number only. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation. Other relevant Directives have to be observed.

CE

APPROVED

Manager:

Date: March 22, 2020

Shenzhen Huawin Testing Certification Co., Ltd.
Add: 7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao'an District, Shenzhen, China
Http://www.huawinlab.com E-mail: info@huawinlab.com

CE CERTIFICATE

CE

Test Report

On Behalf of

Shenzhen Meili Medical Devices Co., Ltd

FFP2 protective mask

Model : FFP2

Prepared for :

Shenzhen Meili Medical Devices Co., Ltd
301Room 301, No. 33, Rifu Road, East District of Baishixia Community, Fuyong Street, Bao'an District, Shenzhen City

Prepared By :

TMC Testing Services (Shenzhen) Co., Ltd.
1st Floor, Block A1, Zone A, Xinshidai Gongrong Industrial Park, No. 2, Shihuan Road, Shiyan Street, Baoan District, Shenzhen, China
Tel: +86-755- 86642861
Web: www.tmc-lab.com
E-mail：Cert@tmc-lab.com

TEST REPORT

EN 149

Respiratory protective devices. Filtering half masks to protect against particles.Requirements,testing,marking

Report Reference No..... :	TMC200314114-S
Checked by (printed name and signature) ... :	Seven Liu
Approved by (printed name and signature) ... :	Lemon Rao
Date of issue.....:	March 20, 2020
Testing laboratory..... :	TMC Testing Services(Shenzhen) Co., Ltd.
Address..... :	1st Floor, Block A1, Zone A, Xinshidai Gongrong Industrial Park, No. 2, Shihuan Road, Shiyan Street, Baoan District, Shenzhen, China
Applicant's name.....:	Shenzhen Meili Medical Devices Co., Ltd
Address..... :	301Room 301, No. 33, Rifu Road, East District of Baishixia Community, Fuyong Street, Bao'an District, Shenzhen City
Manufacturer's name.....:	Shenzhen Meili Medical Devices Co., Ltd
Address..... :	301Room 301, No. 33, Rifu Road, East District of Baishixia Community, Fuyong Street, Bao'an District, Shenzhen City
Factory's name.....:	Same as applicant
Address..... :	
Test specification:	
Standard.....:	☒ EN 149:2001+A1:2009
Test procedure.....:	CE
Non-standard test method.....:	N/A
Test Report Form No..... :	TMC200314114-S
TRF Originator.....:	TMC
Master TRF..... :	Dated 2019-01
Test item description.....:	FFP2 protective mask
Trade Mark.....:	美丽
Model/Type reference..... :	FFP2
Ratings.....:	--

Possible test case verdicts:

- test case does not apply to the test object ... N (Not apply)

- test object does meet the requirement.....P (Pass)

- test object does not meet the requirement.....F (Fail)

Testing .....

Date of receipt of test item ..... March 10, 2020

Date(s) of performance of tests ..... March 10, 2020 to March 21, 2020

General remarks:

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 Issuing testing laboratory.

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

General product information:

N/A

Copy of marking plate:

FFP2 protective mask
Model:FFP2
Standard: EN 149:2001+A1:2009
Classification：FFP2

CE

Shenzhen Meili Medical Devices Co., Ltd

Made in China

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
5	Classification		--
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:		P
	- FFP1		N
	- FFP2	>95%	P
	- FFP3		N
6	Designation		--
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification, option	Particle filtering half mask EN149:2001+A1:2009 FFP2 NR.	P
7	**Requirements**		--
7.1	General		P
	All test all test samples shall meet the requirements.	Compled the requirement, see bellow	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified,the values stated in this European Standard are experature limits.		P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Clear marking is provided, see sample body	P
7.4	Packaging		P
	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.		P
7.5	Material		P
	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.	Comfortable wearing, when releasing no hazards is produced.	P
7.6	Cleaning and disinfecting		N
	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.	It's is not re-usable.	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see append test.	P
7.8	Finish of parts		P
	come into contact with the wearer shall have no sharp edges or burrs		P
7.9	Leakage	See append table 8.5	P
7.9.1	Total inward leakage		P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected.	Enough safe condition is Provide.	P
	Exercise results for total inward leakage shall be not greater than		P
	25％ for FFP1 11％for FFP2 5％ for FFP3	FFP2, Not exceed 11%	P
	And, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than.		P
	22 % for FFP1 8 % for FFP2 2 % for FFP3.	FFP2, Not exceed 8%	P
7.9.2	Penetration of filter material		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	see append table 7.92	P
7.10	Compatibility with shin		P
	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.		P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
7.12	Carbon dioxide content of the inhalation air		P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0% (by volume).	<1.0%	P
7.13	Head harness		P
	Head harness shall be designed can be donned and removed easily and adjustable or selfadjusting and sufficiently robust to hold the particle.	Head harness is donned and removed easily	P
7.14	Field of vision		P
	Field of vision is acceptable in practical performance tests.	Clear field of vsion when wearing	P
7.15	Exhalation valve(s)		N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.	One valve provided	N
	Exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device.	Clearly function	N
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		N
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.		N
7.16	Breathing resistance		P
	Ereathing resistances apply to valved and valveless and shall meet the requirements.		P
7.17	Clogging		N
	General		N

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	For single-use devices clogging test is an optional test.		N
	Devices designed to be resistant to clogging, shown by a slow increase		N
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m^3.		N
7.17.2	Breathing resistance		N
7.17.2.1	Valved particle filtering half masks		N
7.17.2.2	Valveless particle filtering half masks		N
7.17.3	Penetration of filter materia		N
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		N
7.18	Demountable parts		N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No such demountable part	N
8	Testing		--
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.		P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke.	25 cycles/min 2,0 l/stroke.	P
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head,	A saturator incorporated by breathing machine and the dummy head.	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
8.3.2	Temperature conditioning		P
	Exposet masks to the following thermal cycle:		P
	a) for 24 h to a dry atmosphere of (70 ± 3) ℃;		P
	b) for 24 h to a temperature of (-30 ± 3) ℃;		P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	5h to paid for	P
8.3.4	Flow conditioning		P
	A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2.		P
9	Marking		--
9.1	Packaging		P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied, clearly marked	P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.		P
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2, FFP3.	FFP2 NR	P
9.1.4	The number and year of publication of this European Standard.		P
9.1.5	At least the year of end of shelf life.		P
9.1.6	The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.		P
9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.	See product manual	P
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall beadditionally marked with the letter "D".		N
9.2	Particle filtering half mask		P
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:		P
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.	Shenzhen Meili Medical Devices Co., Ltd	P
9.2.2	Type-identifying marking.		P
9.2.3	The number and year of publication of this European Standard.		P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2 NR	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).		N
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		N

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict

Attachments: Test table

Table 7.9.2	Penetration of test aerosol test					P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Sodium chloride test 95 l/min	5.6	5.7	5.5	5.6	5.7	5.6
Paraffin oil test 95 l/min	5.4	5.6	5.7	5.7	5.6	5.5

Table 8.5	Leakage test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
NaCl flow rate (L/min)	90	100	120	110	120
NaCl aerosol (um)	0.3	0.3	0.3	0.3	0.3
0.3Pumping flow rate (L/min)	30	30	30	30	30
NaCl concentration before mask (Mg/m3)	2	2	2	2	2
NaCl concentration after mask (Mg/m3)	0.05	0.06	0.07	0.08	0.06
Note: Test ark volume is $2m^3$ Average Leakage ratio is 8%<11% Calculation formula as below : $P(\%)=\frac{C_2}{C_1}\times\left(\frac{t_{IN}+t_{EX}}{t_{IN}}\right)\times 100$					

Table 8.9.2	Exhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	160	160	160	160	160
Maximum resistance (mbar)	2.45	2.47	2.45	2.46	2.46
Conclusion: Maximum permitted resistance < 3.0 mbar					

Table 8.9.3	Inhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	30	30	30	30	30
Maximum resistance (mbar)	0.42	0.44	0.44	0.45	0.43
Conclusion: Maximum Inhalation resistance < 0.7 mbar					

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict

Table 8.9.3.2	Inhalation resistance test				P
Item \ Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation (L/min)	95	95	95	95	95
Maximum resistance (mbar)	2.12	2.14	2.16	2.15	2.14
Conclusion: Maximum Inhalation resistance < 2.4mbar					

Photo Documentation

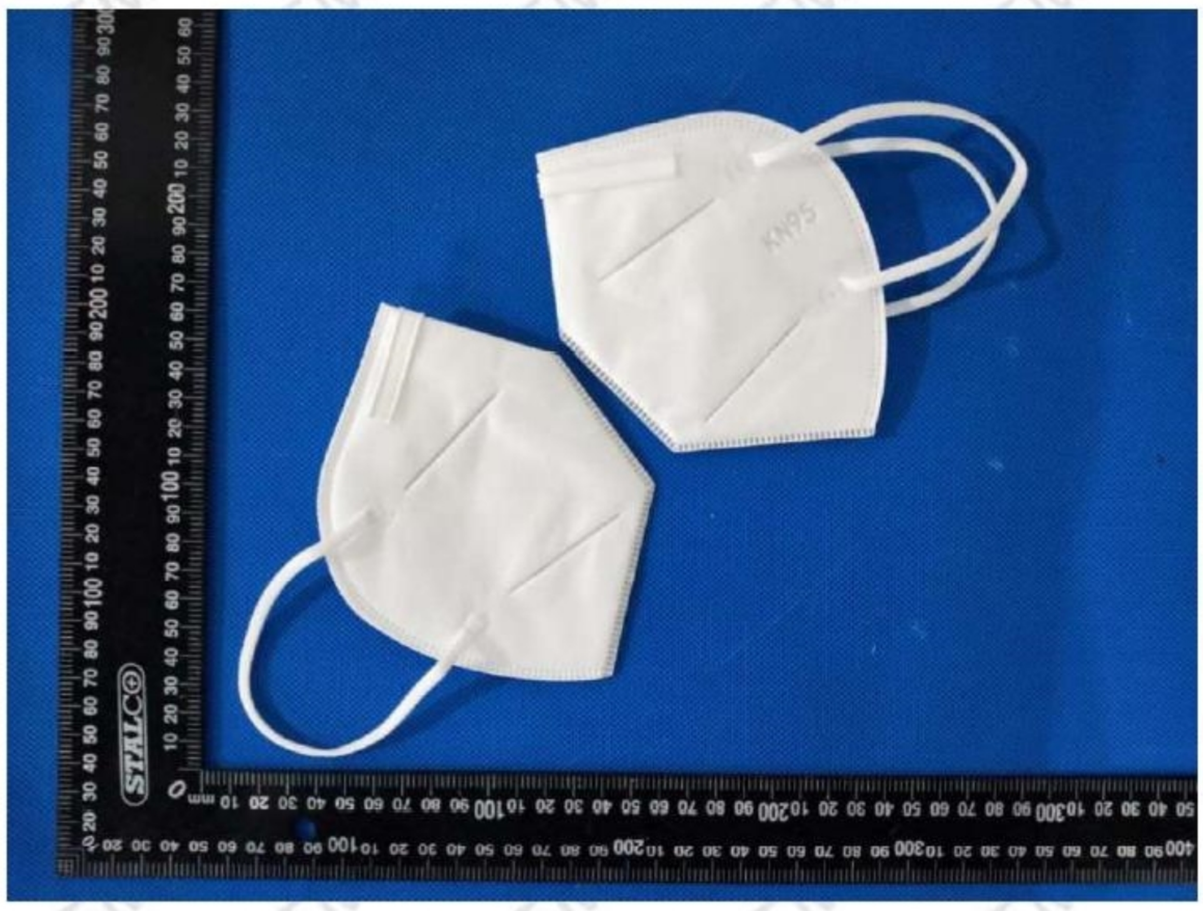


Photo 1 Overview

- End of Test Report -

NIOSH TEST REPORT

https://www.cdc.gov/niosh/npptl/respirators/testing/results/MTT-2020-90.1_International_Shenzhen-Meili_TestReport_Redacted-508.pdf

NPPTL COVID-19 Response: International Respirator Assessment

Evaluation of International Respirators

NPPTL
National Personal Protective Technology Laboratory

Test: Modified TEB-APR-STP-0059

Date Tested: April 29, 2020

Report Prepared: May 2, 2020

Manufacturer: Shenzhen Meili Medical Devices Co., Ltd.

Item Tested: FFP2 Protective Mask

Country of Certification: China (GB2626-2006, EN149:2001+A1:2009)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	12.6	1.71	1.71	98.29
2	85	13.9	41.5	41.5	58.50
3	85	14.6	37.4	37.4	62.60
4	85	13.9	39.3	39.3	60.70
5	85	17.9	35.9	35.9	64.10
6	85	15.7	35.8	35.8	64.20
7	85	14.5	37.9	37.9	62.10
8	85	14.0	1.91	1.91	98.09
9	85	14.7	41.6	41.6	58.40
10	85	14.5	38.5	38.5	61.50
Minimum Filter Efficiency: 58.40				**Maximum Filter Efficiency: 98.29**	

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.

OSVĚDČENÍ O SHODĚ/ STATETMENT OF CONFORMITY/ KOMFORMITATSAUSSAGE

CE

Osvědčení o shodě
Konformitätsaussage
Statement of conformity
Číslo/Nr./No.:01092020/H

Potvrzuji tímto, že uvedený výrobek vyhovuje podmínkám níže uvedených předpisů a norem.
Hiermit wird bestätigt, dass das weiter angeführte Erzeugnis mit den unten angeführten Prüfunterlagen übereinstimmt.
I hereby certify that the product below mentioned meets the below mentioned requirements and standards.

Výrobce:
Hersteller
Manufacturer
Shenzhen Meili Medical Devices Co., Ltd., Čína

Výrobek:
Erzeugnis
Product description
Ochranná maska

Typ/Model:
Typ/Modell
Type/Model
KN95

Ověřeno dle:
Geprüft nach
Tested according to
NEPR 2016/425, ČSN EN 149+A1

Závěrečná zpráva číslo:
Abschlussbericht Nr.
Final report No.
0109202031

ze dne/vom/dated: 2.9.2020

Dne:
Ausgestellt am
Date of issue
2.9.2020

Platnost do: odvolání
Gültig bis widerrufgültig
Expiry date valid until recalled

Conformity consulting s.r.o.
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