REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII **Nr. 049716**

Denumirea autorității de licențiere	**Camera de Licenţiere**
Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență	**Societatea cu Răspundere Limitată „POLISANO PRIM ”** mun. Chişinău, or.Codru, str. Costiujeni, 6/2
Data și numărul certificatului de înregistrare de stat a titularului de licență	14.08.2015
Numărul de înregistrare a întreprinderii sau IDNO	1005600003425
Codul fiscal	
Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența	*** Importul, comercializarea, asistența tehnică şi reparaţia dispozitivelor medicale ***
Data eliberării licenței	25 aprilie 2014
Valabilă pînă la	25 aprilie 2019

Semnătura conducătorului autorității de licențiere

Director adjunct al Camerei de Licenţiere

Eduard HADEI

L.Ș.

Digitally signed by Andronic Iola
Date: 2022.10.12 09:44:59 EEST
Reason: MoldSign Signature
Location: Moldova

Notă: Licența este valabilă numai cu anexa autentificată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.

ANEXĂ LA LICENŢA

Seria A MMII **Nr.** 049716

Titular de licenţă Societatea cu Răspundere Limitată „POLISANO PRIM ”

Titularul de licenţă este obligat să respecte următoarele condiţii de licenţiere pentru desfăşurarea activităţii:

* Importul, comercializarea, asistenţa tehnică şi reparaţia dispozitivelor medicale *

Reperfectată: 20.08.2015

1. Desfăşurarea activităţii licenţiate în conformitate cu cadrul legislativ şi normativ.
2. Asigurarea efectuării controlului metrologic legal a mijloacelor de măsurare, utilizate în domeniul sănătăţii şi siguranţei populaţiei.
3. Indicarea la loc vizibil al preţurilor la mărfuri şi a tarifelor pentru servicii într-o formă clară.
4. Deţinerea autorizaţiei sanitare, antiincendiare, ecologice şi de securitate a muncii.
5. Dispunerea de spaţii cu titlu de proprietate sau de locaţiune pentru desfăşurarea activităţii licenţiate.
6. Dispunerea de specialişti în domeniu (ingineri, bioingineri).

Activitatea licenţiată se desfaşoară pe adresa:
mun. Chişinău, or.Codru, str. Costiujeni, 6/2
Licenţa este valabilă cu următorul specialist - Podoleanu Nicolai

* *

MINISTERUL ECONOMIEI AL REPUBLICII MOLDOVA CAMERA DE LICENŢIERE

L.Ş.

Notă: Anexa şi copiile ei sînt valabile numai cu ştampila originală a autorităţii de licenţiere.

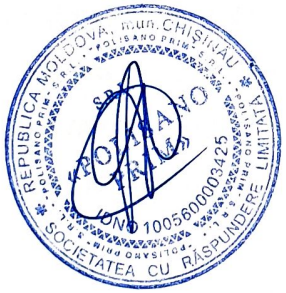
polisano prim
TEHNICĂ MEDICALĂ

Attn.: Public institution „Coordination, Implementation and Monitoring Unit of the Health System Projects"

Hereby, POLISANO PRIM SRL guarantees that the goods offered have their origin in World Bank member country and the certificates of origin will be presented together with the goods at delivery. The shelf life of the goods will be not less than 70% of the total shelf life of the product on delivery.

Director: IOLA ANDRONIC

Date:12/10/2022



MD-2019
Republica Moldova
mun. Chişinău, str. Testemiţanu 3/18
email: directorcomercial@polisanoprim.md
tel/fax: +373 28 57 99

Participant Data

1.	Company name	**„POLISANO PRIM" S.R.L**
2.	Adress	**str. Testemițanu 3/18**
3.	Foundation	**03.02.2005**
4.	Contact phone	**060100102**
5.	Contact person	Iola Andronic
6.	E-mail	marketing@polisanoprim.md

POLISANO PRIM SRL activates for 17 years, winning public procurements, as well as having collaborations in the field of procurement of international projects present in the Republic of Moldova, such as, UN Women (2021,2022), World Bank (2021 project to support the Ministry of Health in the fight against COVID), projects of public associations financed by Embassies on the territory of the Republic of Moldova. The company has extensive experience in the field of public and private procurement, having a history and a reputation for timely completion of all contracts/projects.
The company is the official representative of medical equipment on the territory of the Republic of Moldova, and represent manufacturers such as BTL Industries, AND Japan, TaiDoc Corporation.
The company's activity covers various fields, such as medical devices, consumables, cosmetics, hygiene products, disinfectants, medical furniture, maintenance services and technical support. The manufacturers we collaborate with, are from the Republic of Moldova as well as from Bulgaria, Japan, Taiwan, Germany, Turkey.

MD-2019
Republica Moldova
mun. Chișinău, str. Testemițanu 3/18
email: directorcomercial@polisanoprim.md
tel/fax: +373 28 57 99

I.P. "AGENŢIA SERVICII PUBLICE"
Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS
din Registrul de stat al persoanelor juridice

nr. 5259 din 29.03.2022

Denumirea completă: **Societatea cu Răspundere Limitată «POLISANO PRIM».**
Denumirea prescurtată: **«POLISANO PRIM» S.R.L.**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1005600003425.**
Data înregistrării de stat: **03.02.2005.**
Sediul: **MD-2011, str. Costiujeni, 6/2, or. Codru, mun. Chişinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Activitatea farmaceutică;
2 Comerţul cu ridicata al produselor farmaceutice;
3 Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă;
4 Servicii ale frizeriilor şi alte servicii ale cabinetelor de cosmetică;
5 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
6 Alte tipuri de comerţ cu amănuntul în magazine specializate;
7 Comerţul cu ridicata al altor produse alimentare;
8 Alte tipuri de comerţ cu ridicata;
9 Activităţi de cercetare a pieţei şi de sondaj al opiniei publice;
10 Publicitate;
11 Alte activităţi de servicii prestate în principal întreprinderilor.
Capitalul social: **473221** lei.
Administrator: ANDRONIC IOLA, IDNP 2000001104426,
Asociaţi:
1. LATIŞ OLGA , IDNP 2002028013477
cota 425898.00 lei, ce constituie 90 %
2. ANDRONIC IOLA , IDNP 2000001104426
cota 47322.00 lei, ce constituie 10 %.

Beneficiar efectiv : LATIŞ OLGA , IDNP 2002028013477.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 29.03.2022.

Specialist coordonator **Lazari Aliona**
tel. 022-207-840

CERTIFICATE OF REGISTRATION

认证证书

广东省诺康医疗科技有限公司

统一社会信用代码：91441900MA54B7LE7K

广东省东莞市厚街镇厚街东业路 1 号 301 室

质量管理体系已完成评审并符合

GB/T19001-2016/ISO9001:2015

以下之认证范围

日用口罩（非医用）的生产与销售

颁证日期：**2021 年 01 月 25 日**　　有效日期：**2024 年 01 月 24 日**

首次签发证书日：**2021 年 01 月 25 日**

证书编号：U21Q2GZ8020852R0S

扫码查询证书有效性

获得本认证证书并不意味着证书持有者可以免除其应尽的其他法律义务，当本认证范围中的产品或活动有行政许可要求时，本证书仅在证书持有者的行政许可范围内有效。获证组织须定期接受 GIC 年度监督，并经审核合格方继续有效。请扫描左侧二维码查询证书信息。本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）或 GIC 网站（www.gicg.com.cn）查询

GIC 微信公众号

证书签发：

Guardian Independent Certification Ltd

Registered in England

Sovereign House 212-224 Shaftesbury Avenue London England WC2H 8HQ

Accredited by Member of IAF MLA

0045

CERTIFICATE OF REGISTRATION

The Quality Management Systems of

Guangdong Nuokang Medical Technology Co., Ltd

Unified Social Credit Code:91441900MA54B7LE7K

Room 301, No. 1, Dongye Road, Houjie Town, Dongguan, Guangdong

has been assessed by GIC and complying with

GB/T19001-2016/ISO9001:2015

For the following activities

Daily mask's (Non-medical) production and sales

Date of Issue: **25 January 2021** Date of Expiry: **24 January 2024**

Date of Initial Certification: **25 January 2021**

Certificate No.: U21Q2GZ8020852R0S

Scan for certificate status

The granting of this certificate does not mean that the certificate holder can avoid any legal obligation. If the products or activities covered in the scope of certification require administrative license, the certificate shall be only valid within the scope of administrative licensing. The registered organization shall be subject to regular annual supervision by GIC, and the continual validity of the certificate is base upon conformity of audit. Please scan two-dimension code at lift to find the certificate information. This certificate can be queried at Certification and Accreditation Administration of the People's Republic of China official website (www. cnca.gov.cn) & GIC website (www. gicg.com.cn)

GIC WeChat public number

Signature:

Guardian Independent Certification Ltd

Registered in England

Sovereign House 212-224 Shaftesbury Avenue London England WC2H 8HQ

Accredited by Member of IAF MLA

0045

Technical datasheet

Filtering halfmask **Nuok-9501**

1.0 General Data	
1.1 Manufacturer	Guangdong Nuokang Medical Technology Co., Ltd
1.2 Designation	Nuok-9501 Filtering Half Mask
1.3 Intend of use	Protection against solid and liquid non-volatile particles.
1.4 Relevant standards	EN 149: 2001+A1:2009 FFP2 NR to regulation EU2016/425
1.5 Approval	CE type approval test certificate

2.0 Design and Construction	
2.1 Materials	Non-woven fabric 54% Melt-blown fabric 24,5% Hot air cotton 21,5%
2.2 Construction	The particle filtering half masks NouK-9501 consist of non-woven, Melt-blown , Hot air cotton materials, partly with electrostatical charge
2.3 Working Principle	Particle filtration by combined electrostatically charged and mechanical filter media.
2.4 Shelf Life	2 years
2.5 Dimensions	155*105 mm

3.0 Performance Data	(minimum data in accordance with standard, incl. loading test with paraffin oil and sodium chloride.)	
3.1 Particle filtration efficiency	Test aerosols and minimum efficiency:	sodium chloride: 94 % FFP2, paraffin oil: 94 % FFP2
3.2 Gas filtration capacity	Not applicable.	
3.3 Breathing resistance inhalation	at 30 litres/min, constant flow:	max. 0,7 mbar FFP2
	at 95 litres/min, constant flow:	max. 2,4 mbar FFP2
3.4 Breathing resistance exhalation	at 160 litres/min, constant flow:	max. 3,0 mbar FFP2
3.5 Use Range	It is applicable to the general protection against particles such as dust, PM2.5 haze particles, droplets and so on	

4.0 Documentation	
4.1 Markings	Markings in accordance with EN 149: 2001+A1:2009, expiry date and producer. Approval marking: CE 2163.
4.2 Instructions for use	Each smallest packaging unit of masks is accompanied by an illustrated instruction for use

5.0 Packing & Packaging	
5.1 Packing	Each mask is packed hygienically individually in a single plastic bag.
5.2 Packaging units	50 pcs/box, 20 box/ctn, Total 1000pcs/ctn, Box dimensions: 29.5*16.5*13cm Ctn dimensions: 67*33.5*61cm G.W: 12.8 Kg

6.0 User notes and limitations	
	Guangdong Nuokang Medical Technology Co., Ltd guarantees the performance indicated by the class and type of the filter it is marked with. It must be noted that laboratory values differ from those that can be measured in practise. This may result in longer or shorter break through times. The user must read and understand the instructions for use. Additionally the knowledge of all relevant application rules is vital. Further information on request.

Guangdong Nuokang Medical Technology Co., Ltd

CERTIFICATE OF REGISTRATION
认证证书

广东安辰恩医疗科技有限公司

统一社会信用代码：91441900MA52UM5A50

注册地址：广东省东莞市厚街镇厚街东业路 1 号 101 室
生产地址：广东省东莞市厚街镇厚街东业路 1 号 3 楼

医疗器械质量管理体系已完成评审并符合

YY/T0287-2017/ISO13485:2016

以下之认证范围

一次性使用医用口罩的研发、生产与销售

颁证日期：**2021** 年 **02** 月 **08** 日　　有效日期：**2024** 年 **02** 月 **07** 日

首次签发证书日：**2021** 年 **02** 月 **08** 日

证书编号：G21Q2GZ0525R0S

扫码查询证书有效性

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GIC 微信公众号

证书签发：

卡狄亚标准认证（北京）有限公司

卡狄亚标准认证（北京）有限公司
北京市朝阳区大郊亭中街 2 号院 1 号楼 6 层 1-6D
邮编：100124

CERTIFICATE OF REGISTRATION

The Medical Devices Quality Management Systems of

GUANGDONG ANCHENEN MEDICAL TECHNOLOGY CO.,LTD

Unified Social Credit Code:91441900MA52UM5A50

Registration address:ROOM 101, NO. 1, DONGYE ROAD, HOUJIE TOWN, DONGGUAN, GUANGDONG

Production address:3 FLOOR, NO. 1, DONGYE ROAD, HOUJIE TOWN, DONGGUAN, GUANGDONG

has been assessed by GIC and complying with

YY/T0287-2017/ISO13485:2016

For the following activities

DISPOSABLE MEDICAL MASK'S DEVELOPMENT, PRODUCTION AND SALES

Date of Issue: **08 February 2021** Date of Expiry: **07 February 2024**

Date of Initial Certification: **08 February 2021**

Certificate No.: G21Q2GZ0525R0S

Scan for certificate status

The granting of this certificate does not mean that the certificate holder can avoid any legal obligation. If the products or activities covered in the scope of certification require administrative license, the certificate shall be only valid within the scope of administrative licensing. The registered organization shall be subject to regular annual supervision by GIC, and the continual validity of the certificate is base upon conformity of audit. Please scan two-dimension code at lift to find the certificate information. This certificate can be queried at Certification and Accreditation Administration of the People's Republic of China official website (www. cnca.gov.cn) & GIC website (www. gicg.com.cn)

GIC WeChat public number

Signature: Helen

Guardian Independent Certification (Beijing) Co., Ltd.
1-6D,6F, 1st Building, 2nd Courtyard, Dajiaoting Middle Street,
Chaoyang District, Beijing City
Post. Code: 100124

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE–919/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Guangdong Nuokang Medical Technology Co., Ltd
No.1, DongYe Road, Houjie Town, Dongguan, Guangdong, China

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
NUOKANG /NuoK-9501	FFP2 NR	2163-PPE–919	02.07.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **23/09/2020** and will be valid for one year, until **22/09/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

the QR code

UNIVERSAL CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-919

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Guangdong Nuokang Medical Technology Co., Ltd
No.1, DongYe Road, Houjie Town, Dongguan, Guangdong, China
Continues to fulfil the requirements of

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: NUOKANG **Model:** NuoK-9501
Filtering half mask
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **02/07/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

161019130764

Test Report

Report No.: [2020] WSZ FHL NO.6608

Product Name Filtering half mask

Applicant UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES Trade Co.

Manufacturer Guangdong Nuokang Medical Technology Co.,Ltd

Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co., Ltd.
3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China

检验专用章

Test Report

Product name	Filtering half mask	Model name	NuoK-9501
		Brand	—
Laboratory/ Add.	Jiangsu Guojian Testing Technology Co., Ltd./ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China		
Applicant/ Add/Tel	UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES Trade Co./—/—		
Manufacturer/ Add/Tel	Guangdong Nuokang Medical Technology Co.,Ltd/Room 207, Building 14, No.10 Houjie Huan Hu Road, Houjie Town, Dongguan, Guangdong, China./—		
Sample classification	FFP2	Sample number	GW6608-2020
Sample quantity	130 pcs	Date of receipt of sample	10/06/2020
Test type	Entrusted inspection	Article/Batch/Style number	—
Date (s) of performance of tests	10/06/2020~19/06/2020	Testing location	Same as the Laboratory
Sample state	Meeting the requirements of testing	Sample description	Refer to page 3
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking		
Test items	Packaging, material, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	The samples upon testing comply with FFP2 classification requirements according to the standard EN 149:2001+A1:2009. The details of test results see on Pages 3-11. Date of issue: 24/06/2020		
Note	The test results presented in this report relate only to the submitted sample as received.		

Lu Bing
Approver (name, signature)

Wan Heng
Reviewer (name, signature)

Yang Ying
Chief Tester (name, signature)

Sample description:	—
Test item particulars:	
Type of use ..... :	☐ re-useable particle filtering half mask ☒ single shift only particle filtering half mask
Classes of devices..... :	☐ FFP1 ☒ FFP2 ☐ FFP3
Exhalation valve(s)..... :	☐ Yes ☒ No
Inhalation valve(s)..... :	☐ Yes ☒ No
Designed to protect against both solid &liquid aerosols. :	☒ Yes ☐ No
Possible test case verdicts:	
- Test case does not be required to the test object..... :	NRq（Not required）
- Test case does not apply to the test object..... :	N/A (Not Applicable)
- Test object does meet the requirement..... :	P (Pass)
- Test object does not meet the requirement..... :	F (Fail)

General remarks:

The test results presented in this report relate only to the submitted sample as received.

This report shall not be reproduced, except in full, without the written approval of the issuing Laboratory can provide assurance that parts of a report are not taken out of context.

Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Environmental condition of the testing in this report:

1) Unless otherwise specified, the ambient temperature for testing shall be 25 °C;

2) T.C. Temperature conditioned:

a) for 24 h to a dry atmosphere of 70 °C; b) for 24 h to a temperature of -30 °C;

and return to room temperature 25 °C for 4 h between exposures and prior to subsequent testing.

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result	Single item decision
1 (7.3)	Visual inspection	Marking/ information	—	Marking and the information supplied by the manufacturer, requirements refer to Cl.9 and Cl.10	The clause were not required	NRq
2 (7.4)	Packaging	Visual inspection	—	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.	Particle filtering half masks packaged and protected against mechanical damage and contamination.	Pass
3 (7.5)	Material	Visual inspection	—	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.	Materials were suitable withstand handling and wear.	Pass
			—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1: neither facepiece nor straps have mechanical failure	
					Sample 2: neither facepiece nor straps have mechanical failure	
					Sample 3: neither facepiece nor straps have mechanical failure	
			—	After undergoing S.W. and T.C., none of the particle filtering half masks shall not collapse.	Sample 4: no collapse	
					Sample 5: no collapse	
					Sample 6: no 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.	Not constitute a hazard or nuisance for the wearer	
4 (7.6)	Cleaning and disinfecting		—	Particle filtering half mask designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5.	☐ Fulfil the requirements after testing, or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	N/A
			—	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. Testing shall be done in accordance with 8.11.	☐ Tests results refer to S. No. 7(7.9.2), or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result				Single item decision
5 (7.7)	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1: has the feeling of comfortable wearing				Pass
					Sample 2: has the feeling of comfortable wearing				
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm				
					Sample 2: All fastenings are firm				
		Field of vision	—	Field of vision is acceptable	Sample 1: Having a wider visual field				
					Sample 2: Having a wider visual field				
6 (7.8)	Finish of parts	Visual inspection	—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs				Pass
7 (7.9.2)	Leakage—Penetration of filter material	Sodium chloride	—	≤**6%**	A.R.[1]	0.1%	0.1%	0.1%	Pass
					S.W.[1]	0.1%	0.1%	0.1%	
					M.S+T.C.[2]	0.2%	0.2%	0.2%	
		Paraffin oil	—	≤**6%**	A.R.[1]	1.2%	1.2%	1.1%	Pass
					S.W.[1]	1.3%	1.1%	1.3%	
					M.S+T.C.[2]	2.0%	2.2%	2.1%	
		[1] average penetration over a time of 30s, beginning 3 min after the start of the test reported [2] max. penetration during exposure test reported; Note: The penetration of the filter of the particle filtering half mask shall meet the requirements below: Maximum penetration of sodium chloride aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1% Maximum penetration of paraffin oil aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%							

S.No. (Cl.No.)	Test item	Unit	Technical requirements	Test result		Single item decision
8 (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.	A.R.	5 pcs all don't cause irritation	Pass
				T.C.	5 pcs all don't cause irritation	
9 (7.11)	Flammability	—	When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	A.R.	The Sample is burning. Burning time:0.4s	Pass
					The Sample is burning. Burning time:0.5s	
				T.C.	The Sample is burning. Burning time:0.5s	
					The Sample is burning. Burning time:0.6s	
10 (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). Remark: 3 half masks (S1, S2 and S3) A.R. tested.	Sample 1	0.7011%	Pass
				Sample 2	0.7023%	
				Sample 3	0.7033%	
				average	0.70%	
11 (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 sufficiently robust to hold the particle filtering half mask firmly in position	A.R.	All of 5 pieces particle filtering half mask meet the requirements	Pass
				T.C.	All of 5 pieces particle filtering half mask meet the requirements	
12 (7.14)	Field of vision	—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field		Pass

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result	Single item decision
13 (7.15)	Exhalation valve(s)	Visual inspection	—	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	No exhalation valve(s)	N/A
			—	If an 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 that may be necessary for the particle filtering half mask to comply with 7.9.	No exhalation valve(s)	
		Flow conditioning	—	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	No exhalation valve(s)	
		Strength of attachment of exhalation valve housing	—	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.	No exhalation valve(s)	
14 (7.17)	Clogging— Breathing resistance & Penetration of filter material		—	Optional for single shift use devices, mandatory for re-usable devices. Tested by Cl. 7.17.1/2/3.	☐ Tests results refer to Table C&D, or ☒ Tests not requested for single shift use face mask	N/A
15 (7.18)	Demountable parts		—	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No demountable parts	N/A

Table A- Leakage—Total Inward Leakage

S.No. (Cl.No.)	Test item	Unit	Technical requirements[1)]	Test result							Single item decision
				Exercises	E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	
16 (7.9.1)	Leakage—Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than **11%**; And in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than **8%.**	A.R.	4.2	5.5	5.8	5.9	4.6	5.2	Pass
					5.1	6.1	6.2	7.1	5.6	6.0	
					4.4	5.8	6.3	6.3	4.8	5.5	
					4.3	4.8	5.7	5.8	4.0	4.9	
					3.8	4.5	5.1	5.2	3.9	4.5	
				T.C.	4.7	5.3	5.5	6.0	4.4	5.2	
					3.8	4.3	4.4	5.3	3.8	4.3	
					5.2	5.9	6.6	7.0	5.4	6.0	
					5.1	5.7	6.3	6.7	5.1	5.8	
					3.8	4.4	5.2	5.3	3.6	4.5	

Note 1:
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
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.

Table A-1- Test subjects—Facial dimension

Test Subject No.	Length of face (mm)	Width of face (mm)	Depth of face (mm)	Width of mouth (mm)
1	120	130	109	59
2	122	140	115	65
3	119	160	139	55
4	112	122	119	63
5	110	130	118	60
6	115	119	110	59
7	112	123	113	55
8	103	130	100	50
9	118	139	130	63
10	120	135	125	50

Table B- Breathing Resistance

S.No. (Cl.No.)	Test item		Unit	Technical requirements[1)]	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
17 (7.16)	Breathing resistance	Inhalation 30 L/min	mbar	≤0.7	A.R.	0.7	0.6	0.6	0.7	0.7	Pass
						0.7	0.7	0.7	0.7	0.6	
						0.6	0.6	0.7	0.6	0.7	
					S.W.	0.7	0.7	0.7	0.6	0.7	
						0.6	0.7	0.6	0.7	0.7	
						0.6	0.6	0.7	0.7	0.6	
					T.C.	0.7	0.6	0.7	0.7	0.7	
						0.6	0.7	0.6	0.7	0.6	
						0.7	0.7	0.7	0.6	0.7	
		Inhalation 95 L/min		≤2.4	A.R.	2.1	2.1	2.2	2.2	2.1	Pass
						2.2	2.1	2.1	2.1	2.1	
						2.1	2.2	2.1	2.2	2.2	
					S.W.	2.1	2.2	2.1	2.1	2.1	
						2.2	2.1	2.2	2.1	2.2	
						2.1	2.1	2.1	2.2	2.1	
					T.C.	2.2	2.1	2.2	2.1	2.2	
						2.1	2.1	2.1	2.2	2.1	
						2.1	2.2	2.1	2.1	2.1	
		Exhalation 160 L/min		≤3.0	A.R.	2.8	2.9	2.8	2.8	2.8	Pass
						2.8	2.8	2.8	2.8	2.8	
						2.9	2.8	2.9	2.7	2.9	
					S.W.	2.8	2.9	2.8	2.8	2.8	
						2.9	2.8	2.9	2.8	2.8	
						2.8	2.8	2.8	2.9	2.7	
					T.C.	2.8	2.9	2.8	2.8	2.8	
						2.8	2.8	2.8	2.8	2.9	
						2.9	2.8	2.9	2.9	2.8	

Note 1: Limitation may need be changed according to classification, refer to Table 2 — Breathing resistance of EN 149:2001 +A1:2009 for the Technical requirements.

Table C- Clogging Test—Breathing resistance

S.No. (Cl.No.)	Test item[1) 2)]		Unit	Technical requirements[1) 2)] (mbar)	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
18 (7.17)	Clogging test— Breathing resistance	Inhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						
		Exhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						

Note 1: Valved particle filtering half masks

After clogging the inhalation resistances shall not exceed FFP1: 4 mbar FFP2: 5 mbar FFP3: 7 mbar at 95 l/min continuous flow;

The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Note 2: Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed FFP1: 3 mbar, FFP2: 4 mbar FFP3: 5 mbar at 95 l/min continuous flow.

Table D- Clogging Test—Penetration of filter material

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result		Single item decision
19 (7.17)	Clogging test- Penetration of filter material	Paraffin oil	—	—	A.R.		N/A
					T.C.		
					T.C.		

Note: Maximum penetration of test aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%

Abbreviations :		
A.R. As received	M.S. Mechanical strength	S.W. Simulated wearing treatment
T.C. Temperature conditioned	F.C. Flow conditioned	C.D. Cleaning and Disinfecting

Annex A- Estimates of the uncertainty of measurement

Test item	Uncertainty
Total inward leakage	2.98%
Penetration of filter material	1.00%
Flammability	1.00%
Carbon dioxide content of the inhalation air	0.93%
Breathing resistance	1.90%

Annex B- Sample Photo

The end