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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1795

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

TRN MODA TEKSTİL SAN. VE TİC. LTD. ŞTİ.

Selahaddin Eyyübi Mah. 1538 Sok. No :32/4 34517 Esenyurt / İstanbul TURKEY

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

Single use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 4 layered, without valve, ear straps and adjustable nose bar.

Brand Name: TRN MedTeks
Model: TRNMT-NRFM002
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 **16/12/2020** 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

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 15.12.2020 / 2163-KKD-1795

Manufacturer: TRN MODA TEKSTİL SAN. VE TİC. LTD. ŞTİ.

Address: Selahaddin Eyyübi Mah. 1538 Sok. No :32/4 34517 Esenyurt / İstanbul TURKEY

Introduction

This report is for the, given above, manufacturer prepared according to the test results obtained from Universal Certification And Surveillance Services Trade Co., dated 13.12.2020 with Serial Id 12-2020-T0575 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 25 October 2020 (Revision 00) provided by the manufacturer.

The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

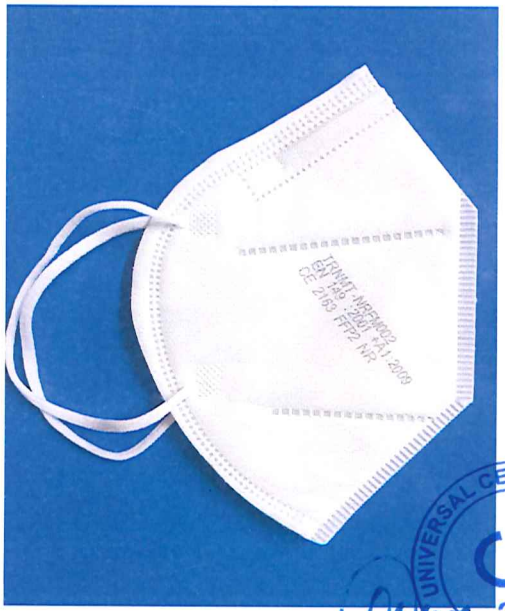
Product Description: Single use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 4 layered, without valve, ear straps and adjustable nose bar.

Component and Materials:

Component	Material	Grade
Outer Layer	Spunbond fabric	50 g/m^2
Filter Layer I	Hot air cotton fabric	60 g/m^2
Filter Layer II	Melt-blown fabric	25 g/m^2
Inner Layer	Spunbond fabric	30 g/m^2
Ear Strap	Spandex+Nylon	Width 5+/- 1mm Lenght : 200+ 20 mm
Nose Bridge	Polypropylene+ Galvanized iron wire	Width 5+/- 1mm Diameter : 0.5+/-0.02 mm

Classification: FFP2 NR

Brandname: TRN MedTeks **Model:** TRNMT-NRFM002



UNIVERSAL CERTIFICATION CE 2163 Notified Body

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

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ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT

1.1. Design principles

1.1.1. Ergonomics

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest possible level.

1.1.2. Levels and classes of protection

1.1.2.1. Highest level of protection possible

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2. Innocuousness of PPE

1.2.1. Absence of risks and other inherent nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

1.2.1.3. Maximum permessible user impediment

Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

1.3 Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

1.4. Information supplied by the manufacturer

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
g) The type of packaging suitable for transport;
h) The significance of any markings(see 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination

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2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.
The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.
If necessary, such PPE must be treated or provided with means to prevent misting-up.
Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.
If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.
Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.
The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.
Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.
If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.
The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.
The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.
The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.
The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.
In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.

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Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

Conforming to EN 149:2001 + A1:2009 Standard Requirements	
Article 5	Classification: Particle Filtering Half Mask The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as; Filtering Efficiency and Maximum Total Inward Leakage: Classified as FFP2 Mask is classified for single shift use, NR
Article 7.4	**Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report.
Article 7.5	**Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users. Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.
Article 7.6	**Cleaning and Disinfection:** Particle filtering half mask is **not** designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer.
Article 7.7	**Practical Performance:** The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfactions reported during total inward tests about the comfort, field of vision and fastening issues.

Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result
2.Head harness comfort	2	0	Positive results are obtained from the test subjects **No imperfections**
3.Security of fastenings	2	0	
5.Field of vision	2	0	

Conditioning: (A.R.) As Received, original

Article 7.8	**Finish of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.
Article 7.9.1	**Total Inward Leakage:** The Total Inward Leakage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the conduction of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each excersize are available in the test report. It was reported that: All 50 exercise measurement results are smaller or equal to 11%, the values varies between 7,23% and 7,98%. All 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 7,58% and 7,72%. **According to the reported results, the product meets the limits for FFP2 classification.**

Article 7.9.2

Penetration of filter material: Sodium Chloride Testing

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	36	0,86	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1 and FFP2** classes.
(A.R.)	37	1,05		
(A.R.)	38	0,95		
(S.W.)	1	0,99		
(S.W.)	2	1,01		
(S.W.)	3	1,03		
(M.S. T.C.)	10	0,98		
(M.S. T.C.)	11	0,96		
(M.S. T.C.)	12	0,90		

Conditioning: (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

95 L/min = 1,6 $dm^3.sn^{-1}$

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Article 7.9.2

Penetration of filter material: Paraffin Oil Testing

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	39	1,88	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1 and FFP2** classes.
(A.R.)	40	2,03		
(A.R.)	41	1,93		
(S.W.)	4	1,95		
(S.W.)	5	1,99		
(S.W.)	6	1,96		
(M.S. T.C.)	13	1,97		
(M.S. T.C.)	14	2,01		
(M.S. T.C.)	15	1,99		

Conditioning: (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

Article 7.10

Compatibility with skin: In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.

Article 7.11

Flammability:

Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	45	Burn for 0.0s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	**Passed** Filtering half masks fulfill requirements of the standard
(A.R.)	46	Burn for 0.0s		
(T.C.)	21	Burn for 0.0s		
(T.C.)	22	Burn for 0.1s		

Conditioning: (A.R.) As Received, original
(T.C.) Temperature Conditioning

Article 7.12

Carbon dioxide content of the inhalation air:

Condition	No. of Sample	CO_2 content of the inhalation air [%] by volume	An average CO_2 content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	26	0,45	0,48 [%]	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	**Passed** Filtering half masks fulfil requirements of the standard
(A.R.)	27	0,52			
(A.R.)	28	0,47			

Conditioning: (A.R.) As Received, original

Article 7.13

Head harness: In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.

Article 7.14

Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is weared.

Article 7.15

Exhalation Valve(s):
The model under inspection have no valves.
Passed.

Article 7.16

Breathing Resistance: Inhalation

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temparature conditioning and 3 simulated wearing treatment conditioned complies with the limits given in the standard for FFP1 FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.

Passed.

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Article 7.17	**Clogging:** This test is not applied to Particle Filtering Half Mask which is not reusable. ***(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)***
Article 7.18	**Demountable Parts:** There are no demountable parts on the product.
Article 8	**Testing:** All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask.
Article 9	**Marking – Packaging:** Necessary markings are available on the product package (box). The name and trademark of the manufacturer is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the year of end of shelf life, using and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified Section 9.1 on the technical file. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing TRNMT-NRFM002. The mask marking indicates that the mask will carry information about the brandname (TRN MedTeks) of the manufacturer, type of mask, the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. The tested samples by the laboratory carry necessary marking information as stated in the technical documentation, the manufacturer shall also follow marking instruction in the technical file for serial production. Model TRNMT-NRFM002 drawing exists in the technical file Section 6 of the manufacturer.
Article 10	**Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file Section 8 found to be appropriate,The manufacturer shall include this documented user information text in every smallest commertially available package.

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert	**Suat KAÇMAZ** Director

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UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO.
Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY

TEST REPORT

Report Date:13.12.2020
Report Number: 12-2020-T0575

CLIENT and SAMPLE INFORMATION

TEST OWNER	TRN MODA TEKSTİL SAN. VE TİC. LTD. ŞTİ.		
ADDRESS	Selahaddin Eyyübi Mah. 1538 Sok. No :32/4 34517 Esenyurt / İstanbul		
SAMPLE DESCRIPTION	Folding type protective mask		
BRAND NAME – MODEL	TRN MedTeks / TRNMT-NRFM002		
TESTING STANDARD	EN 149:2001+A1:2009		
CASE NUMBER	CE-PPE-3749		
SAMPLE RECEIVE DATE	23.11.2020	TESTING START DATE	23.11.2020
DISINFECTION INSTRUCTION *If applicable*	Not given, single use only		
NUMBER OF SAMPLES	50	SAMPLE IDs:	1 – 46
AS RECEIVED SAMPLE NO	26-46		
CONDITIONING SAMPLE NO	Simulated wearing treatment	1-2-3-4-5-6-7-8-9 (As Received)	
	Temperature conditioning	10-11-12-13-14-15 (Sample after test of Mechanical Strength)	
		16-17-18-19-20-21-22-23-24-25 (As Received)	
	Mechanical strength	10-11-12-13-14-15 (As Received)	

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1. *REPORT SUMMARY*

TEST STANDARD	*TEST NAME*	*RESULT*	*EVALUATION*
EN 149:2001 + A1:2009 clause 8.5 EN 13274-1:2001	Total Inward Leakage Testing	**Pass**	**FFP2**
EN 149:2001 + A1:2009 clause 8.11 EN 13274-7:2019	Penetration of Filter Material	**Pass**	**FFP2**
EN 149:2001 + A1:2009 clause 8.6 EN 13274-4:2001	Flammability Testing	**Pass**	**See results**
EN 149:2001 + A1:2009 clause 8.7 EN 13274-6:2001	Carbon Dioxide Content of The Inhalation Air Testing	**Pass**	**See results**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Breathing Inhalation Resistance-30 l/min	**Pass**	**See results**
	Breathing Inhalation Resistance-95 l/min	**Pass**	**See results**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Exhalation Resistance, flow rate 160 l/min	**Pass**	**See results**

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2. *TEST RESULTS and EVALUATION*

7.4 PACKAGING (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Clause 8.2-Visual inspection

REQUIREMENT	RESULTS	COMMENT
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.	Pass	The masks were packaged in sealed plastic bags, in larger plastic bags inside a large cardboard box that gave some protection against mechanical damage or contamination before use

Lab A

7.5 MATERIAL (EN 149:2001 + A1:2009 clause 8.2, 8.3.1, 8.3.2)

Test Method: Clause 8.2-Visual inspection

Clause 8.3.1-Simulated wearing treatment

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask was mounted on a Sheffield dummy head.

For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head.

The air has been saturated at (37 ± 2) °C at the mouth of the dummy head

Clause 8.3.2-Temperature conditioning

The ambient temperature for testing has been between 16 °C and 32 °C and the temperature limits has been subject to an accuracy of ±1 °C.

a) for 24 h to a dry atmosphere of (70 ± 3) °C;

b) for 24 h to a temperature of (-30 ± 3) °C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning has been carried out in a manner which ensures that no thermal shock occurs.

REQUIREMENT	RESULTS	COMMENT
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.	Pass	The materials used were able to withstand handling and wear during the limited laboratory testing carried out.
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Pass	It was 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.	Pass	None of the specimens conditioned suffered mechanical failure.
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass	None of the specimens had not collapse after conditioning.

Lab B

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7.6 CLEANING AND DISINFECTING (EN 149:2001 + A1:2009 clause 8.4, 8.5, 8.11)

Test Method: Described in Clause 8.4, 8.5 and 8.11

REQUIREMENT	RESULTS	COMMENT
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.	N/A	This article is not applicable for tested protective mask which is single use disposable mask.

7.7 PRACTICAL PERFORMANCE (EN 149:2001 + A1:2009 clause 8.4)

Test Method: Described in Clause 8.4

REQUIREMENT	RESULTS	COMMENT
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that can not be determined by the tests described elsewhere in this standard. Two as received mask samples are used by two subject for the walking (10 mins walking with a speed of 6km/h) and work simulation (bended walking, crawling and basket filling exercises) tests.	No imperfections	Detail refer to Annex I

Annex I-Test Result:

Number of sample: 29 (A.R), 30 (A.R)

Assessed elements	Positive Assessment	Negative Assessment	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
The face piece fitting Head harness comfort Security of fastenings Field of vision	2 2 2 2	0 0 0 0	Filtering half masks should not have imperfections related to wearer's acceptance	Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.7 No imperfections

The subjects (MEG and MA) were able to complete the exercises and did not report any nuisance or problem with the mask.

Lab B

7.8 FINISH OF PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

REQUIREMENT	RESULTS	COMMENT
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Pass	None of the specimens used in laboratory testing showed evidence of sharp edges or burrs while visual inspection and performance tests.

Lab A

7.9.1 TOTAL INWARD LEAKAGE (EN 149:2001 + A1:2009 clause 8.5)

Test Method: Described in Clause 8.5

REQUIREMENT	RESULTS	COMMENT
The total inward leakage consists of three components: face seal leakage, exhalation value leakage (if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual results 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 not be greater than: 22 % for FFP1, 8 % for FFP2, 2 % for FFP3	Pass	Classified as FFP2 Detail refer to Annex II

Annex II-Test Result:

The test results obtained are given in the tables as follows

Test Subject	No of sample	Cond.	1. Walk (%)	Head side/ side (%)	Head up/down (%)	Talk (%)	2. Walk (%)	Average (%)
1	31	A.R.	7.23	7.41	7.62	7.77	7.89	7.58
2	32	A.R.	7.31	7.52	7.69	7.79	7.96	7.65
3	33	A.R.	7.33	7.54	7.72	7.85	7.94	7.67
4	34	A.R.	7.35	7.55	7.71	7.82	7.93	7.67
5	35	A.R.	7.29	7.53	7.75	7.86	7.91	7.66
6	16	T.C.	7.34	7.60	7.71	7.84	7.95	7.68
7	17	T.C.	7.33	7.57	7.69	7.81	7.97	7.67
8	18	T.C.	7.31	7.60	7.72	7.83	7.95	7.68
9	19	T.C.	7.38	7.62	7.75	7.89	7.98	7.72
10	20	T.C.	7.34	7.63	7.72	7.85	7.92	7.69
All 50 individual exercise results were not greater than 11 % All 10 individual wearer arithmetic means were not greater than 8 %.								Pass (FFP2)

Test Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	117	155	130	60
2	113	148	128	62
3	112	160	134	59
4	115	148	125	61
5	120	158	132	57
6	118	150	134	59
7	115	152	130	57
8	117	155	134	59
9	114	149	128	57
10	110	150	131	55

For Information Only

Lab B

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7.9.2 PENETRATION OF FILTER MATERIAL (EN 149:2001 + A1:2009 clause 8.11)

Test Method: Described in Clause 8.11

REQUIREMENT	RESULTS	COMMENT
<table><tr><th rowspan="2">Classification</th><th colspan="2">Max penetration of test aerosol</th></tr><tr><th>NaCl test 95 l/min %max</th><th>Paraffin oil test 95 l/min %max</th></tr><tr><td>FFP1</td><td>20</td><td>20</td></tr><tr><td>FFP2</td><td>6</td><td>6</td></tr><tr><td>FFP3</td><td>1</td><td>1</td></tr></table>	Pass	Detail refer to Annex IIIA and IIIB

Annex IIIA-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Penetration of Sodium Chloride in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
36	As received	0.86	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first and second protection class (FFP1, FFP2)
37		1.05		
38		0.95		
1	Simulated wearing treatment	0.99		
2		1.01		
3		1.03		
10	Mechanical strength + Temperature conditioned	0.98		
11		0.96		
12		0.90		

Annex IIIB-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Penetration of Paraffin Oil Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
39	As received	1.88	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first and second protection classes (FFP1, FFP2)
40		2.03		
41		1.93		
4	Simulated wearing treatment	1.95		
5		1.99		
6		1.96		
13	Mechanical strength + Temperature conditioned	1.97		
14		2.01		
15		1.99		

Lab A + B

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7.10 COMPATIBILITY WITH SKIN (EN 149:2001 + A1:2009 clause 8.4, 8.5)

Test Method: Described in Clause 8.4 and 8.5.

REQUIREMENT	RESULTS	COMMENT
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.	Pass	No irritation or any other adverse effect to health or sensitivity reported by the subjects during the practical performance and TIL tests.

Lab B

7.11 FLAMMABILITY (EN 149:2001 + A1:2009 clause 8.6)

Test Method: Described in Clause 8.6

REQUIREMENT	RESULTS	COMMENT
The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn 5s after removal from the flame.	Pass	Detail refer to Annex IV

Annex IV-Test Result: The test results obtained are given in the tables as follows:

No. of Sample	Condition	Visual inspection	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
45	As received	0,0 s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.11
46		0,0 s		
21	Temperature conditioned	0,0 s		
22		0,1 s		

Lab B

7.12 CARBON DIOXIDE CONTENT OF THE INHALATION AIR (EN 149:2001 + A1:2009 clause 8.7)

Test Method: Described in Clause 8.7

REQUIREMENT	RESULTS	COMMENT
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Pass	Detail refer to Annex V

Annex V-Test Result: The test results obtained are given in the tables as follows:

No. of Sample	Condition	CO_2 content of the inhalation air [%] by volume	An average CO_2 content of the inhalation air [%] by volume	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
26	As received	0,45	0,48	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.12
27		0,52			
28		0,47			

Lab B

7.13 HEAD HARNESS (EN 149:2001 + A1:2009 clause 8.4, 8.5)

Test Method: Described in Clause 8.4, 8.5

REQUIREMENT	RESULTS	COMMENT
The head harness shall be designed so that the particle filtering half-mask can be donned and removed easily.	Pass	No problem with the head harness reported by the wearers during the practical performance test.
The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and capable of maintaining total inward leakage requirements for the device.	Pass	No problem with the head harness reported by the wearers during the practical performance test.

Lab B

7.14 FIELD OF VISION (EN 149:2001 + A1:2009 clause 8.4)

Test Method: Described in Clause 8.4

REQUIREMENT	RESULTS	COMMENT
The field of vision is acceptable if determined so in practical performance tests.	Pass	There were no adverse comments following practical performance tests.

Lab B

7.15 EXHALATION VALVE (EN 149:2001 + A1:2009 clause 8.2, 8.3.4, 8.8, 8.9.1)

Test Method: Clause 8.2, 8.3.4, 8.8, 8.9.1

REQUIREMENT	RESULTS	COMMENT
A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	N/A	No exhalation valve in tested samples.
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	N/A	No exhalation valve in tested samples.
Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30s.	N/A	No exhalation valve in tested samples.
When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10s.	N/A	No exhalation valve in tested samples.

Lab -

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7.16 BREATHING RESISTANCE (EN 149:2001 + A1:2009 clause 8.9)

Test Method: Described in Clause 8.9

REQUIREMENT	RESULTS	COMMENT
<table><tr><td rowspan="2">Classification</td><td colspan="3">Max permitted resistance (mbar)</td></tr><tr><td colspan="2">Inhalation</td><td>Exhalation</td></tr><tr><td></td><td>30 l/min</td><td>95 l/min</td><td>160 l/min</td></tr><tr><td>FFP1</td><td>0.6</td><td>2.1</td><td>3.0</td></tr><tr><td>FFP2</td><td>0.7</td><td>2.4</td><td>3.0</td></tr><tr><td>FFP3</td><td>1.0</td><td>3.0</td><td>3.0</td></tr></table>	Pass	Detail refer to Annex VIA-VIB

Annex VIA-Test Result:
The test results obtained are given in the tables as follows:

Inhalation Resistance

No. of Sample	Condition	Inhalation Resistance (mbar)				
		Flow rate 30 l/min [mbar]	Requirements in accordance with EN 149:2001+A1:2009	Flow rate 95 l/min [mbar]	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
42	As received	0,50	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	1,34	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed Qualifies FFP1, FFP2, FFP3
43		0,53		1,37		
44		0,49		1,37		
7	Simulated wearing treatment	0,52		1,40		
8		0,50		1,39		
9		0,51		1,41		
23	Temperature conditioned	0,49		1,36		
24		0,50		1,38		
25		0,49		1,37		

Exhalation Resistance

No. of Sample	Condition	Flow rate	Facing directly	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
42	As received	160l/min	1,65	1,69	1,71	1,72	1,74	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed Qualifies FFP1, FFP2, FFP3
43			1,71	1,71	1,72	1,75	1,78		
44			1,69	1,67	1,70	1,71	1,72		
7	Simulated wearing treatment		1,63	1,68	1,69	1,70	1,75		
8			1,68	1,70	1,73	1,74	1,78		
9			1,65	1,72	1,76	1,71	1,73		
23	Temperature conditioned		1,60	1,64	1,68	1,70	1,72		
24			1,58	1,65	1,63	1,69	1,73		
25			1,56	1,62	1,65	1,64	1,68		

Lab A

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7.17 CLOGGING (EN 149:2001 + A1:2009 clause 8.9, 8.10)

Test Method: Described in Clause 8.8, 8.10

REQUIREMENT	RESULTS	COMMENT
Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1:4mbar, FFP2:5mbar, FFP3:7mbar at 95L/min continuous flow. The exhalation resistance shall not exceed 3mbar at 160L/min continuous flow. Valveless particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1:3mbar, FFP2:4mbar, FFP3:5mbar at 95L/min continuous flow	NAs	This is optional test and not desired by client.

Lab -

7.18 DEMOUNTABLE PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

REQUIREMENT	RESULTS	COMMENT
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	N/A	No demountable part.

Lab -

Pass	*Requirement satisfied.*
NCR	*Requirement not satisfied. Refer to the "Result details" section for more information.*
NAs	*Assessment not carried out.*
N/A	*Requirement not applicable.*

LABORATORY INFORMATION

Code	Laboratory Name	Competency Explanations
Lab A	UNIVERSAL SERTIFIKASYON VE GOZETIM HIZMETLERI TIC. LTD. STI.	Internal Laboratory Services of Notified Body
Lab B	GCNTR ULUSLARARASI BELGELENDIRME, GOZETIM, EGITIM VE DIS TICARET LIMITED SIRKETI KOCAELI DILOVA SUBESI	Laboratory holds an accreditation by Turkish Accreditation Agency with number AB-1252-T according to EN ISO/IEC 17025:2017.

- The laboratories are contracted bodies with UNIVERSAL CERTIFICATION and the technical competence of the laboratories is also under supervision / assessment of UNIVERSAL CERTIFICATION based on the provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and services standard.
- Each test result given in this test report shown with the issuing laboratory code.

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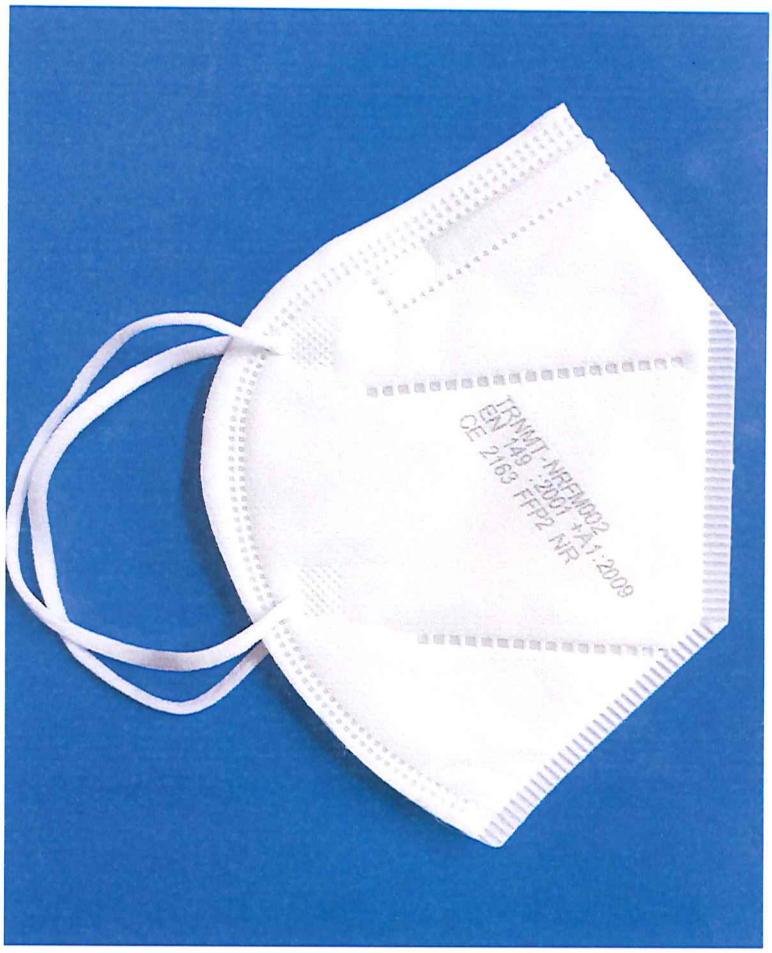
Sample Photo



- End of Report -

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POTRDILO

NB 2163

CERTIFIKAT O EU-PREGLEDU TIPA

Št. potrdila: 2163-PPE-1795

Oprema za zaščito dihal, filtrirne polmaske za zaščito pred delci, ki jih proizvaja

TRN MODA TEKSTiL SAN. VE TiC. LTD. STi.

Selahaddin Eyylibi Mah. 1538 Sok. No :32/4 34517 Esenyurt / istanbul TUR.

-EN 149:2001 + Al:2009 Oprema za zaščito dihal - Filtrirne polmaske za zaščito pred delci - Zahteve, preskušanje, označevanje

Na podlagi opravljenega pregleda tipa z oceno poročil o preskusih in tehnične dokumentacije v skladu s Prilogo 5 k Uredbi o osebni zaščitni opremi (EU) 2016/425 se potrdi, da izdelek izpolnjuje zahteve uredbe.

Opredelitev izdelka

Polobrazna maska za filtriranje delcev za enkratno uporabo za zaščito pred trdnimi in tekočimi aerosoli je zložljiva, štiriplastna, brez ventila, ušesnih trakov in nastavljivega nosnega nosilca.

Ime blagovne znamke: TRN MedTeks
Model: TRNMT-NRFM002
Razvrstitev: FFP2 NR

V tem primeru lahko proizvajalec uporabi številko priglašenega organa (2163) in namesti oznako CE, kot je prikazano spodaj, na zgoraj navedene modele izdelkov kategorije ill;

- izdaja ustrezne izjave EU o skladnosti v skladu z **Uredbo o osebni zaščitni opremi (EU) 2016/425, Priloga 9.**
- stalno uspešno izpolnjevanje zahtev iz **Uredbe o** osebni zaščitni **opremi (EU) 2016/425** in harmoniziranih standardov, zagotovljeno z ocenami na podlagi **Priloge 7 (modul C2) ali Priloge 8 (modul D) k** uredbi najpozneje eno leto od začetka serijske proizvodnje

Ta certifikat je bil prvotno izdan **16. 12. 2020** in bo veljal pet let, če se ustrezni harmonizirani standard ne bo spremenil in ne bo vplival na bistvene zdravstvene in varnostne zahteve.

CE
2163

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POROČILO O TEHNIČNI OCENI

DATUM POROČILA/Č: 15.12.2020 / 2163-KKD-l 795

Proizvajalec: TRN MODA TEKSTIL SAN. VE TiC. LTD. STi.

Naslov: Selahaddin Eyyi.ibi Mah. 1538 Sok. No :32/4 34517 Esenyurt / istanbul TURČIJA

Uvod

To poročilo je za zgoraj navedenega proizvajalca pripravljeno v skladu z rezultati preskusov, pridobljenimi od družbe Universal Certification And Surveillance Services Trade Co. , z dne 13.12.2020 s serijsko številko ld 12-2020-T0575 na podlagi standarda EN 149: 2001 + A **1:** 2009 in tehnične dokumentacije z dne 25. oktobra 2020 (revizija 00), ki jo je predložil proizvajalec.

Tehnična dokumentacija proizvajalca in ocena tveganja glede na bistvene zdravstvene varnostne zahteve ter poročilo o preskusu so ocenjeni glede na njihovo povezavo z Uredbo o bistvenih zahtevah za osebno varovalno opremo in ugotovljeno je bilo, da so ustrezni.

To poročilo je priloga in sestavni del certifikata o EU-pregledu tipa, izdanega proizvajalcu. Rezultati preskusa in izdani certifikat pripadajo samo preskušanemu modelu. Tehnično poročilo obsega skupno 6 strani.

Opis izdelka: je zložljiva, štirislojna, brez ventila, ušesnih trakov in nastavljivega nosnega nosilca.

Sestavni deli in materiali:

Komponenta	Material	Gracie
Zunanji sloj	Tkanina Spunbond	50 g/ rrf
Plast filtra T	Bombažna tkanina z vročim zrakom	60 glrrf
Filter Layer TI	Tkanina, ki se raztaplja in piha	25 g/rrf
Notranji sloj	Tkanina Spunbond	30 g/m'
Trak za uho	Spandeks + najlon	Širina 5+/- 1 mm Dolžina: 200+ 20 mm
Nosni most	Polipropilen + pocinkana železna žica	Širina 5+/- I mm Premer: 0,5+/-0,02 mm

Razvrstitev: FFP2 NR

Blagovna znamka: TRN MedTeks **Model:** TRNMT-NRFM002

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1.1. Načela oblikovanja

1.1.1. Ergonomija

Osebna varovalna oprema mora biti načrtovana in izdelana tako, da lahko uporabnik v predvidljivih pogojih uporabe, za katere je namenjena, normalno opravlja dejavnost, povezano s tveganjem, pri tem pa uživa ustrezno zaščito na najvišji možni ravni.

1.1.2. Ravni in razredi zaščite

1.1.2.1. Najvišja možna raven zaščite

Optimalna raven zaščite, ki jo je treba upoštevati pri načrtovanju, je tista, nad katero bi omejitve zaradi nošenja osebne varovalne opreme preprečile njeno učinkovito uporabo v času izpostavljenosti tveganju ali običajnega izvajanja dejavnosti.

1.1.2.2. Razredi zaščite, ki ustrezajo različnim ravnem tveganja

Kadar so različni predvidljivi pogoji uporabe takšni, da je mogoče razlikovati več ravni istega tveganja, je treba pri načrtovanju osebne varovalne opreme upoštevati ustrezne razrede zaščite.

1.2. Neškodljivost osebne varovalne opreme

1.2.1. Odsotnost tveganj in drugih dejavnikov, ki so neločljivo povezani s težavami

Osebna varovalna oprema mora biti načrtovana in izdelana tako, da v predvidljivih pogojih uporabe izključuje tveganja in druge moteče dejavnike.

1.2.1.1. Primerni sestavni materiali

Materiali, iz katerih je izdelana osebna varovalna oprema, vključno z vsemi možnimi produkti razgradnje, ne smejo negativno vplivati na zdravje ali varnost uporabnikov.

1.2.J .2. Zadovoljivo stanje površine vseh delov osebne varovalne opreme, ki so v stiku z uporabnikom

Vsi deli osebne varovalne opreme, ki so v stiku ali lahko pridejo v stik z uporabnikom, ko je ta oblečen, ne smejo imeti hrapavih površin, ostrih robov, ostrih konic in podobnega, kar bi lahko povzročilo čezmerno draženje ali poškodbe.

1.2.1.3. Ma"<najmanjša dopustna ovira za uporabnika

Vse ovire, ki jih Osebna varovalna oprema povzroča pri gibanju, drži in čutnem zaznavanju, morajo biti čim manjše: Osebna varovalna oprema ne sme povzročati gibanja, ki bi ogrožalo uporabnika ali druge osebe.

1.3 Udobje in učinkovitost

1.3.1. Prilagoditev osebne varovalne opreme morfologiji uporabnika

Osebna varovalna oprema mora biti načrtovana in izdelana tako, da omogoča pravilno namestitev na uporabnika in da ostane na svojem mestu v predvidljivem času uporabe. ob upoštevanju dejavnikov okolja, dejanj, ki jih je treba opraviti, in položajev, ki jih je treba zavzeti. V ta namen mora biti mogoče osebno varovalno opremo prilagoditi morfologiji uporabnika z vsemi ustreznimi sredstvi, kot so ustrezni sistemi prilagajanja in pritrjevanja ali zagotavljanje ustrezne palete velikosti.

1.3.2. Lahkotnost in trdnost zasnove

Osebna varovalna oprema mora biti čim lažja, ne da bi to vplivalo na trdnost in učinkovitost konstrukcije.

Poleg posebnih dodatnih zahtev, ki jih morajo izpolnjevati, da zagotavljajo ustrezno zaščito pred zadevnimi tveganji (glej 3), mora biti Osebna varovalna oprema sposobna prenesti učinke pojavov v okolju, ki so značilni za predvidljive pogoje uporabe.

1.4. Informacije, ki jih zagotovi proizvajalec

Opombe, ki jih mora pripraviti prvi in predložiti ob dajanju osebne varovalne opreme na trg, morajo vsebovati vse pomembne informacije o:

a) Poleg imena in naslova proizvajalca in/ali njegovega pooblaščenega zastopnika, ustanovljenega v Skupnosti
b) Skladiščenje, uporaba, čiščenje, vzdrževanje. servisiranje in razkuževanje. čiščenje. vzdrževanje ali dezinfekcijska zaščita, ki jo priporočajo proizvajalci, ne sme škodljivo vplivati na osebno varovalno opremo ali uporabnike, če se uporablja v skladu z ustreznimi navodili:
c) Uspešnost, zabeležena med tehničnimi preskusi za preverjanje ravni ali razredov zaščite, ki jih zagotavlja gostujoča osebna varovalna oprema:
d) Primerni dodatki za osebno varovalno opremo in značilnosti ustreznih rezervnih delov:
e) Razredi zaščite, ki ustrezajo različnim ravnem tveganja, in ustrezne omejitve uporabe:
t) Rok zastarelosti ali obdobje zastarelosti osebne varovalne opreme ali nekaterih njenih sestavnih delov:
g) vrsta embalaže, primerne za prevoz:
b) pomen morebitnih oznak (glejte 2.12).
i) Kjer je to primerno, se sklicevanja na direktive uporabljajo v skladu s členom 5(6)(b):
j) Ime, naslov in identifikacijska številka priglašenega organa, vključenega v fazo načrtovanja osebne varovalne opreme

Te opombe, ki morajo biti natančne in razumljive, morajo biti na voljo vsaj v uradnem(-ih) jeziku(-ih) namembne države članice.

2. DODATNE ZAHTEVE, KI SO SKUPNE VEČ RAZREDOM ALI VRSTAM PPE

2.1. Osebna varovalna oprema, ki vključuje sisteme za prilagajanje

Če Osebna varovalna oprema vključuje sisteme za nastavitev, morajo biti ti zasnovani in izdelani tako, da se po nastavitvi v predvidljivih pogojih uporabe ne odklopijo nenamerno.

2.3. Osebna varovalna oprema za obraz, oči in dihala

Osebna varovalna oprema čim bolj omejuje uporabnikov obraz, oči, vidno polje ali dihalni sistem.

Zasloni za te vrste osebne varovalne opreme morajo imeti stopnjo optične nevtralnosti, ki je združljiva s stopnjo natančnosti in trajanjem dejavnosti uporabnika.

Po potrebi je treba takšno osebno varovalno opremo obdelati ali opremiti s sredstvi, ki preprečujejo zameglitev.

Modeli osebne varovalne opreme, namenjeni uporabnikom, ki potrebujejo korekcijo vida, morajo biti združljivi z nošenjem očal ali kontaktnih leč.

2.4. Osebna varovalna oprema, ki se stara

Če je znano, da lahko staranje bistveno vpliva na konstrukcijsko učinkovitost nove osebne varovalne opreme, je treba na vsakem kosu osebne varovalne opreme, danem na trg, in na njegovi embalaži neizbrisno in nedvoumno označiti mesec in leto izdelave in/ali, če je mogoče, mesec in leto zastarelosti.

Če se proizvajalec ne more zavezati glede življenjske dobe osebne varovalne opreme, morajo njegova navodila vsebovati vse potrebne informacije, da lahko kupec ali uporabnik določi mesec in leto zastarelosti ob upoštevanju ravni kakovosti modela ter dejanskih pogojev skladiščenja, uporabe, čiščenja, servisiranja in vzdrževanja.

Če je verjetno, da je opazno in hitro poslabšanje učinkovitosti osebne varovalne opreme posledica staranja zaradi redne uporabe postopka čiščenja, ki ga priporoča proizvajalec, mora proizvajalec, če je to mogoče, na vsak kos osebne varovalne opreme, dan na trg, namestiti oznako, ki navaja največje število postopkov čiščenja, ki se lahko izvedejo, preden je treba opremo pregledati ali zavreči. Če taka oznaka ni nameščena, mora proizvajalec to informacijo navesti v svojih navodilih.

2.6. Osebna varovalna oprema za uporabo v potencialno eksplozivnih atmosferah

Osebna varovalna oprema, namenjena za uporabo v potencialno eksplozivnih atmosferah, mora biti načrtovana in izdelana tako, da ne more biti vir električnega, elektrostatičnega ali udarnega obloka ali iskre, ki bi lahko povzročila vžig eksplozivne zmesi.

2.8. Osebna varovalna oprema za posredovanje v zelo nevarnih razmerah

Navodila, ki jih proizvajalec diete priloži osebni varovalni opremi za posredovanje v zelo nevarnih situacijah, morajo vsebovati zlasti podatke, namenjene usposobljenim in izobraženim osebam, ki so usposobljene za njihovo razlago in zagotavljanje njihove uporabe s strani uporabnika.

V navodilih mora biti opisan tudi postopek, ki ga je treba sprejeti, da se preveri, ali je osebna varovalna oprema pravilno nastavljena in funkcionalna, ko jo nosi uporabnik. Kadar PPE vključuje alarm, ki se sproži, če ni zagotovljene običajne ravni zaščite, mora biti alarm zasnovan in nameščen tako, da ga lahko uporabnik zazna v predvidljivih pogojih uporabe.

2.9. Osebna varovalna oprema z elementi, ki jih lahko uporabnik prilagodi ali odstrani.

Kadar PPE vključuje sestavne dele, ki jih lahko uporabnik pritrdi, prilagodi ali odstrani zaradi zamenjave, morajo biti taki sestavni deli načrtovani in izdelani tako, da jih je mogoče enostavno pritrditi, prilagoditi in odstraniti brez orodja.

2.12. Osebna varovalna oprema z eno ali več identifikacijskimi ali prepoznavnimi oznakami, ki se neposredno ali posredno nanašajo na zdravje in varnost

Identifikacijski ali razpoznavni znaki, ki se neposredno ali posredno nanašajo na zdravje in varnost, pritrjeni na te vrste ali razrede, morajo biti po možnosti v obliki usklajenih piktogramov ali ideogramov in morajo ostati popolnoma čitljivi ves čas predvidljive življenjske dobe osebne varovalne opreme. Poleg tega morajo biti te oznake popolne, natančne in razumljive, da se prepreči kakršna koli napačna razlaga: zlasti kadar take oznake vsebujejo besede ali stavke, morajo biti ti napisani v uradnem(-ih) jeziku(-ih) države članice, v kateri se oprema uporablja.

Če je osebna varovalna oprema (ali njen sestavni del) premajhna, da bi bilo mogoče pritrditi le del potrebne oznake, je treba ustrezne informacije navesti na embalaži in v opombah proizvajalca.

3. DODATNE ZAHTEVE, SPECIFIČNE ZA POSAMEZNA TVEGANJA.

3.10.1. Zaščita dihal

Osebna varovalna oprema, namenjena zaščiti dihalnega sistema, mora uporabniku omogočati dovajanje zraka za dihanje, kadar je izpostavljen onesnaženemu ozračju in/ali ozračju z nezadostno koncentracijo kisika.

Zrak za dihanje, s katerim PPE oskrbuje umrlega uporabnika, je treba pridobiti na ustrezen način, na primer po filtriranju onesnaženega zraka skozi PPE ali z dovajanjem iz zunanjega neonesnaženega vira.

Sestavni materiali in drugi sestavni deli teh vrst osebne varovalne opreme morajo biti izbrani ali načrtovani in vgrajeni tako, da zagotavljajo ustrezno dihanje in higieno dihanja uporabnika za obdobje nošenja v predvidljivih pogojih uporabe.

Tesnost obrazne maske in padec tlaka pri vdihu in pri filtrirnih napravah mora zmogljivost čiščenja zagotavljati, da je prodor onesnaževal iz onesnaženega ozračja dovolj majhen, da ne škoduje zdravju ali higieni uporabnika.

Osebna varovalna oprema mora vsebovati podrobnosti o posebnih značilnostih opreme, ki skupaj z navodili usposobljenemu in kvalificiranemu uporabniku omogočajo pravilno uporabo osebne varovalne opreme.

Pri filtrirni opremi morajo biti v navodilih proizvajalca navedeni tudi roki za skladiščenje nove embalaže.

filters kept in their original

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Tehnična ocena standarda EN 149: 200 I +AI: 2009 in drugih standardov, na katere se sklicuje, klavzule, ki ustrezajo Direktivi (EU) 20 I 6/425

Skladnost s standardnimi zahtevami EN 149:2001 + A1:2009

Razvrstitev: Filtriranje delcev Polomastna maska

Člen 5

Maska, ki se ocenjuje na podlagi rezultatov preskusov in tehnične dokumentacije, ki jo je predložil proizvajalec, se razvrsti kot; Učinkovitost filtriranja in največje skupno uhajanje navzven: Maska je razvrščena za uporabo v eni izmeni. NR

Člen 7.4

Pakiranje: Da bi jih pred uporabo zaščitili pred onesnaženjem, so polmaske za filtriranje delcev zapakirane v kartonske škatle, ki preprečujejo onesnaženje, **mehanske poškodbe.** Za **zasnovo embalaže in** izdelek velja, da je odporna proti predvidljivim pogojem uporabe na podlagi vizualnih rezultati pregleda, navedeni v poročilu o preskusu.

Material: Glede na rezultate simulirane obdelave pri nošenju in temperaturnega kondicioniranja se razume, da je odporna na rokovanje in obrabo v obdobju, za katerega je namenjena polmaska za filtriranje delcev.

Člen 7.5

kakršna koli snov iz filtrirnega medija, ki se sprošča iz zraka skozi filter, ne predstavlja nevarnosti ali **za uporabnika. Proizvajalec** izjavlja, da materiali, uporabljeni pri izdelavi maske, nimajo škodljivega vpliva na uporabnika. zdravje in varnost uporabnikov.

Na podlagi rezultatov preskusa se maske niso razpadle, ko so bile izpostavljene simuliranemu nošenju in temperaturnim pogojem. Nobena neprijetna situacija ni

i::ported du,ing praktično perforn1a '=ts s človeškimi subjekti.

Člen 7.6

Čiščenje in razkuževanje: Polmaska za filtriranje delcev **ni** zasnovana tako, da bi jo bilo mogoče ponovno uporabiti. Postopek čiščenja ali razkuževanja ni predviden.

proizvajalec.

Praktična izvedba:

Iz poročila o preskusu je razvidno, da ljudje niso imeli nobenih težav pri izvajanju vaj, ko so bili oblečeni v vzorčne **maske, pri preskusu hoje ali** preskusih **simulacije dela.** Uporabniki niso poročali o nobenih težavah pri udobnosti naglavnih pasov/trakovov/ušesnih zank, varnosti zapenjanja in vidnem polju. Prav tako med skupnimi notranjimi preskusi niso poročali o nobenih pomanjkljivostih glede udobja, varnosti zapenjanja in vidnega polja.

Člen 7.7

vprašanja.

Ocenjeni elementi	Pozitivna	Negativni	Zahteve v skladu s standardom EN 149:2001 + AI:2009 in Rezultat
2.Head harness udobje	2	0	Pozitivni rezultati so pridobljeni od testnih oseb **Brez pomanjkljivosti**
3.Varnost pritrdilnih elementov	2	0	
5.Field of vision	2	0	

itioning: (R.) Kot prejeto. original

Člen 7.8

Končna obdelava delov: ki lahko pridejo v stik z uporabnikom. nimajo ostrih robov in ne vsebujejo brusi.

Skupna notranja najemnina:

Preskus skupnega notranjega uhajanja opravi IO posameznik v aerosolni komori s trakom za hojo, vzorci pa se odvzamejo med izvajanjem vaj, opredeljenih v standardu. Vzorci, uporabljeni pri preskusu, se kondicionirajo v skladu s standardom kot temperaturno kondicioniranje in tako, kot so bili prejeti. Navedene so tudi dimenzije obraza preiskovancev. Podatki o meritvah za vsakega udeleženca in za za vsak izlet so na voljo v testnem repu1t.

Člen 7.9.1

Poročali so, da:

Vsi rezultati meritev 50 vaj so manjši ali enaki 11 %. vrednosti se gibljejo med 7,23 % in 7,98 %. Aritmetična sredina vseh IOposameznikov je manjša ali enaka 8 %. vrednosti se gibljejo med 7,58 % in 7,72 %.

Glede na ponovno pridobljene rezultate 1irodukt izpolnjuje omejitve za razvrstitev FFP2.

Penetracija filtrirnega materiala: Preskus z natrijevim kloridom

Stanje	Število Samole	Testiranje natrijevega kloiida 95 Umin max (%)	Zahteve v skladu z EN 149:2001 + A1:2009	Rezultat
(A. R.)	36	0.86	FFPI :0:20% FFP2 :'" 6 % FFP3 :'"I%	Filtrirne polmaske izpolnjujejo zahteve standarda ENEN 149:2001 +Al:2009 b ven v 7.9.2 v območju razredov FFPl in FFP2. 95 L/min = 1,6 dm^3 .sn-'
(A. R.)	37	1.05		
(A. R.)	38	0.95		
(S.W.)	I	0.99		
(S.W.)	2	1.01		
(S.W.)	3	1.03		
/M.S. T. C.I	10	0.98		
/M.S. T. C.)	11	0.96		
(M.S. T. C.	12	0.90		

Člen 7.9.2

Kondicioniranje: (M.S.) Mehanska moč

(T.C.) Temperaturno kondicioniranje

(A. R.) Kot je bilo prejeto. original

(S.W.) Simulirano nošenje tr.: atment

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Penetracija filtrirnega materiala: Preskus parafinskega olja

Stanje	Število Samole	Testiranje parafinskega olja 95 L/min max (%)	Zahteve v skladu z EN 149:2001 +Al:2009	Rezultat
(A. R:i	39	1.88		
(A.R.)	40	2.03		
(A.R:i	41	1.93	FFPI :5 20 %	Filtrirne polmaske izpolnjujejo zahteve standarda EN EN 149:200 I +AI:2009 iz točke 7.9.2 v območju **FFPI in Fl.P2**.
cs.w:i	4	1.95		
rs. w:i	5	1.99	FFP2 :56 %	
fSW)	6	1.96		
(M.S. T.C.I	13	1.97	FFP3 :5 I%	
(M.S.T.C.)	14	2.01		
(M.S.T.C.)	15	1.99		

Anic/e 7.9.2

Anicle 7.10

Cond1t1on111g: (M.S.) Mechamcal Strength
(T.C.) Temperanire Conditioning
(A.R.) As Received. original
(S.W.) Simulirana obdelava z nošenjem

Združljivost s kožo: Verjetnost, da bi materiali maske v stiku s kožo povzročili draženje ali druge škodljive učinke na zdravje, v poročilu o praktičnem učinku ni bila ocenjena.

Anicle 7.11

Vnetljivost:

Stanje	Število Samole	Vizualni pregled	Zahteve v skladu z EN 149:200 I +AI:2009	Rezultat
(A.R.)	45	Bum za 0,0 s	Filtriranje polovične maske ne sme bum ali ne se še naprej trudite za več kot 5 s po odstranitvi iz plamena	**Sprejeto**
(A. R.)	46	Bum za 0,0 s		
(T. C.)	21	Bum za 0,0 s		Polmaske za filtriranje izpolnjujejo zahteve standard
(T.C.)	22	Bum za0.ls		

Cond1t1onmg: (A.R.) As Received. ongmal
(T.C.) Temperature Conditioning

Člen 7.12

Vsebnost ogljikovega dioksida v vdihanem zraku:

Stanje	Št. vzorca	CO, vsebnost CO v zraku za vdihavanje [%] glede na prostornino	**Povprečna** vsebnost CO, vsebnost pri vdihavanju **zra k**	**Zahteve v skladu z** EN 149:200 I +AI:2009	Rezultat
(A.R.)	26	0.45	0.48 [%]	vsebnost CO v zraku za vdihavanje ne presega povprečno 1,0 % prostornine	**Sprejeto** Filtriranje polovičnih mask izpolnjevati zahteve standarda.
(A. R.)	27	0.52			
(A.R.)	28	0,47			

Anicle 7.13

Pogoji: (A .) Kot Re::_ived. izvirnik

Varnostni pas za glavo: Rezultati teh preskusov kažejo, da ušesne zanke/glavni pasovi dovolj dobro držijo masko.

Člen 7.14

Vidno polje: V poročilu o praktičnem učinku niso poročali o neželenih učinkih na razpoložljivost vidnega polja pri uporabi maske.

Člen 7.15

Ventil(-i) za izdih:
Pregledani model nima ventilov. Sprejeto.

Odpornost pri dihanju: Vdihavanje

Člen 7.16

Skupna ocena na slikah, zbranih za 9 različnih vzorcev 3, kot je bilo prejeto. 3 s kondicioniranjem glede na temperaturo in 3 s simulirano obdelavo glede na obrabo, ki je bila kondicionirana, je v skladu z mejnimi vrednostmi iz standarda za razrede FFPI FFP2 in FFP3. To velja za rezultate vdihavanja za 30 Umin. 95 Umin in izdihovanje pri 160 Umin.

Sprejeto.

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Arllcle 7.17

Zamašitev: Ta preskus se ne uporablja za polmasko Panicle Filtering Half Mask, ki ni za večkratno uporabo.

(Foir11gle ,\-/.ift uporaba 1/t:I,led. ,-. c/og;.:iug te. ,-t ix optimwl test. Za ponovno uporabo 1/e1-ice. ,- te. ,-t i. ,-mfimlatory.)

Člen 7.18

Odstranljivi deli: Na izdelku ni odstranljivih posod.

Člen 8

Testiranje: Vsi preskusi, opravljeni v skladu s členom 8 tega standarda, so na voljo v poročilu o preskusu in so ocenjeni v tem poročilu za kvalifikacijo in razvrstitev maske.

Označevanje - pakiranje: Potrebne oznake so na voljo na embalaži izdelka (škatli). Ime in blagovna znamka proizvajalca sta jasno vidna. Vrsta maske in razvrstitev, vključno s statusom ponovne uporabe. sklicevanje na standard EN 149:200 I +A I :2009. leto izteka roka uporabnosti. navodila za uporabo in shranjevanje ter piktogrami in oznaka CE so na voljo na embalaži izdelka. Zgornja ocena temelji na tehničnem dokumentu za pakiranje in označevanje. za oblikovanje škatle. Preverite oddelek 9.1 tehnične dokumentacije.

Člen 9

Tehnična dokumentacija za zasnovo maske (risba) je bila ocenjena tudi glede zahtev za označevanje. risba TRNMT-NRFM002. Označevanje maske pomeni, da bo maska nosila informacije o blagovni znamki (TRN MedTeks) proizvajalca, vrsti maske, sklicevanju na standard EN I 49+A I :2009 in razvrstitvi, vključno z možnostjo ponovne uporabe maske. Proizvajalec natisne tudi oznako CE s številko našega priglašenega organa. Maska nima podsklopov. Preskusni vzorci, ki jih je preskusil laboratorij, imajo potrebne informacije o označevanju, kot je navedeno v tehnični dokumentaciji. proizvajalec upošteva tudi navodila za označevanje v tehnični dokumentaciji za serijsko proizvodnjo. Risba vzorca TRNMT NRFM002 obstaja v tehnični dokumentaciji proizvajalca, oddelek 6.

Anic/e 10

Informacije, ki jih zagotovi proizvajalec: V vsaki najmanjši komercialno dostopni embalaži izdelka. izvajanje (navodila za vgradnjo). nadzor pred uporabo. opozorila in omejitve uporabe, skladiščenje in pomen simbolov/piktogramov so opredeljeni. Dokument z navodili za uporabnike v tehnični dokumentaciji v oddelku 8 se šteje za ustreznega. proizvajalec vključi to dokumentirano besedilo z informacijami za uporabnike vsaki najmanjši trgovini lbravailabl<!J)!'ckage.

PRIPRAVIL

Osman CAMCI
Strokovnjak za osebno varovalno opremo

POTRJENO S STRANI

SuatKA";:MAZ
Direktor

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UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO.
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POROČILO O TESTU

Datum poročila: 13.12.2020 **Številka poročila:** l 2-2020-T0575

PODATKI O KLIENTU IN VZORCU

LASTNIK TESTA	TRN MODA TEKSTiL SAN. VE TiC. LTD. $Ti.		
NASLOV	Selahaddin Eyy-Ubi Mah. 1538 Sok. No :32/4 34517 Esenyurt / istanbul		
OPIS VZORCA	Zložljiva zaščitna maska		
IME BLAGOVNE ZNAMKE - MODEL	TRN MedTeks / TRNMT-NRFM002		
STANDARD ZA TESTIRANJE	EN 149:200l+Al:2009		
ŠTEVILKA ZADEVE	CE-PPE-3749		
DATUM PREJEMA VZORCA	23.11.2020	DATUM ZAČETKA TESTIRANJA	23_ 11.2020
NAVODILA ZA RAZKUŽEVANJE *Če je primerno*	Ni podano, samo za enkratno uporabo		
ŠTEVILO VZORCEV	50	ID vzorca:	1-46
KOT JE PREJEL VZOREC ŠT.	26-46		
VZOREC ZA KONDICIONIRANJE ŠT.	Simulirana obdelava z nošenjem	1-2-3-4-5-6-7-8-9 (po prejemu)	
	Temperaturno prilagajanje	10-11-12-13-14-15 (Vzorec po testu mehanske moči!!!)	
	[illegible]	16-17-18-19-20-21-22-23-24-25 (po prejemu)	
	Mehanska trdnost	10-11-12-13-14-15 (po prejemu)	

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1. *POVZETEK POROČILA*

TESTNI STANDARD	*IME TESTA*	*REZULTAT*	*OCENJEVANJE*
EN 149:2001 + A1:2009, klavzula 8.5 EN 13274-1:2001	Testiranje skupnega notranjega uhajanja	**Prehod**	**FFP2**
EN 149:2001 + A1:2009, klavzula 8.11 EN 13274-7:2019	Penetracija filtrirnega materiala	**Prehod**	**FFP2**
EN 149:2001 + A1:2009, klavzula 8.6 EN 13274-4:2001	Testiranje vnetljivosti	**Prehod**	**Oglejte si rezultate**
EN 149:2001 + A1:2009, klavzula 8.7 EN 13274-6:2001	Vsebnost ogljikovega dioksida v vdihanem zraku	**Prehod**	**Oglejte si rezultate**
EN 149:2001 + Al:2009 klavzula 8.9 EN 13274-3:2001	Dihalni upor pri vdihavanju - 30 I/min	**Prehod**	**Oglejte si rezultate**
	Dihalni upor pri vdihavanju-95 I/min	**Prehod**	**Oglejte si rezultate**
EN 149:2001 + A1:2009, klavzula 8.9 EN 13274-3:2001	Upor pri izdihu, pretok 160 1/m v	**Prehod**	**Oglejte si rezultate**

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2. *REZULTATI TESTOV IN OCENJEVANJE*

7.4 EMBALAŽA (EN 149:2001 + Al:2009, klavzula 8.2)

Preskusna metoda: Določba 8.2-Vizualni pregled

REOUIREMENT	REZULTATI	KOMENTAR
Polmaske za filtriranje pm1icle se ponujajo za prodajo pakirane tako, da so pred uporabo zaščitene pred mehanskimi poškodbami in onesnaženjem.	Prehod	Maske so bile zapakirane v zaprtih plastičnih vrečkah. v večjih plastičnih vrečkah v veliki kartonski škatli, ki je dajala nekaj zaščita pred mehanskimi poškodbami ali onesnaženjem pred uporabo

Laboratorij A

7.5 **MATERIAL (EN 149:2001 + Al:2009, klavzula 8.2, 8.3.1, 8.3.2)**

Preskusna metoda: Določba 8.2 - Vizualni pregled Določba 8.3.1 - Simulirana obdelava pri obrabi

Dihalni aparat je nastavljen na 25 ciklov/min in 2,0 I/strok. Polmaska za filtriranje delcev je bila nameščena na glavo Sheffieldove lutke.

Za preskušanje je v linijo za izdih med dihalnim aparatom in glavo preskusne lutke vgrajen saturator, ki je nastavljen na temperaturo, višjo od 37 °C, da se zrak ohladi, preden doseže usta glave preskusne lutke.

Zrak je bil nasičen na (37 ± 2) °C v ustju glave ščipalke Klavzula 8.3.2 - Temperaturno kondicioniranje

Temperatura okolice za preskušanje je bila med 16 °C in 32 °C, temperaturne meje pa so bile natančne do ±1 °C.

a) 24 ur v suhi atmosferi pri (70 ± 3) °C;

b) 24 ur na temperaturo (-30 ± 3) °C; med posameznimi izpostavitvami in pred nadaljnjim testiranjem pustite, da se povrne na sobno temperaturo vsaj 4 ure. Kondicioniranje je bilo izvedeno na način, ki zagotavlja, da ne pride do toplotnega šoka.

REOUIREMENT	REZULTATI	KOMENTAR
Uporabljeni materiali morajo biti primerni, da prenesejo rokovanje in obrabo v obdobju, za katerega je polmaska za filtriranje delcev namenjena.	Prehod	Uporabljeni materiali so bili med omejenim laboratorijskim preskušanjem odporni na rokovanje in obrabo.
Vse snovi iz filtrirnega medija, ki se sprostijo iz zraka. pretok skozi filter ne sme biti nevaren ali moteč za uporabnika.	Prehod	Za uporabnika ni predstavljal nevarnosti ali nadloge.
Po kondicioniranju, opisanem v 8.3.1, nobena od pol mask za filtriranje delcev ne sme imeti je prišlo do mehanske okvare obrazne maske ali trakov.	Prehod	Pri nobenem od kondicioniranih vzorcev ni prišlo do mehanske okvare.
Če je pogojeno v skladu z 8.3.1 in 8.3.2, se polmaska za filtriranje delcev ne sme zrušiti.	Prehod	Noben od vzorcev se po kondicioniranju ni zrušil.

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7.6 ČIŠČENJE IN RAZSTRANJEVANJE (EN 149:2001 + A 1 :2009, točke 8.4, 8.5, 8.11)

Preskusna metoda: Opisano v točkah 8.4, 8.5 in **8.11**

ZAHTEVA	REZULTATI	KOMENTAR
Če je polmaska za filtriranje delcev zasnovana za večkratno uporabo, morajo biti uporabljeni materiali odporni na sredstva in postopke za čiščenje in razkuževanje, ki jih določi proizvajalec. V skladu s točko 7.9.2. mora polobrazna maska za filtriranje delcev po čiščenju in razkuževanju, ki jo je mogoče ponovno uporabiti, izpolnjevati zahteve glede penetracije ustreznega razreda.	*NIA*	Ta članek se ne uporablja za testirane zaščitne maske, ki so maske za enkratno uporabo.

7.7 PRAKTIČNA UČINKOVITOST (EN 149:2001 + Al:2009, klavzula 8.4)

Preskusna metoda: Opisano v točki 8.4

ZAHTEVA	REZULTATI	KOMENTAR
Na polmaski za filtriranje delcev se opravijo praktični preskusi delovanja v realnih razmerah. Ti splošni preskusi so namenjeni preverjanju opreme glede pomanjkljivosti, ki jih ni mogoče ugotoviti s preskusi, opisanimi drugje v tem standardu. Dva prejetega vzorca maske sta dva preiskovanca uporabila za teste hoje (I 0 minut hoje s hitrostjo 6 km/h) in simulacije dela (upognjena hoja, plazenje in vaje za polnjenje košare).	Brez pomanjkljivosti	Podrobnosti glejte v Prilogi T

Priloga I - Rezultat preskusa:

Število vzorcev: 29 (A.R.). 30 (A.R.)

Ocenjeni elementi	Pozitivna ocena	Negativna ocena	Zahteve v skladu z EN 149:200 I+Al :2009	Ocenjevanje rezultata testa Skladnost / Neskladje s predpisi
Prileganje obraznega dela Udobje pri nošenju glave Varnost zapenjanja Vidno polje	2 2 2 2	0 0 0 0	Filtrirne maske halr ne smejo imeti pomanjkljivosti, povezanih z uporabnikovim sprejem	Filtrirne polmaske izpolnjujejo zahteve standarda EN 149:2001 + Al:2009 iz točke 7.7 Brez pomanjkljivosti

7.8 KONČNA OBLIKA DELOV (EN 149:2001 + Al:2009, točka 8.2)

Preskusna metoda: Opisano v točki 8.2

REOU!REMENT	REZULTATI	KOMENTAR
Deli naprave, ki lahko pridejo v stik z uporabnikom, ne smejo imeti ostrih robov ali odlomkov.	Prehod	Med vizualnim pregledom in preskusi delovanja noben od vzorcev, uporabljenih pri laboratorijskem preskušanju, ni pokazal ostrih robov ali odrezkov.

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7.9.1 CELOTNA ZUNANJA TEKOČNOST (EN 149:2001 + Al:2009, klavzula 8.5)

Preskusna metoda: Opisano v točki 8.5

ZAHTEVA	REZULTATI	KOMENTAR
Celotno notranje uhajanje je sestavljeno iz treh delov: obrazno morje. uhajanje I, uhajanje vrednosti izdiha (če je vrednost izdiha vgrajena) in prodor filtra. Za polmaske, ki filtrirajo delce in so nameščene v skladu s podatki proizvajalca, vsaj 46 od 50 posameznih rezultatov ne sme biti več kot: 25 % za FFP I. 11 % za FFP2. 5 % za FFP3 in poleg tega vsaj 8 od 10 posameznih aritmetičnih sredin uporabnika za skupno uhajanje navznoter ne sme biti večje od: 22 % za FFPl. 8 % za FFP2. 2 % za FFP3	Preh od	Razvrščeno kot FFP2 Podrobnosti glejte v Prilogi II

Priloga II - Rezultat preskusa:

Dobljeni rezultati preskusov so prikazani v naslednjih preglednicah

Predmet preizkusa	Število vzorcev	Pogoj.	1. Hoja (%)	Stran glave/stran (%)	Dvig/spust glave (%)	Pogovori (%)	2. Hoja (%)	Povprečje (%)
	31	A.R.	7.23	7.41	7.62	7.77	7.89	7.58
2	32	A. R.	7.31	7.52	7.69	7.79	7.96	7.65
3	33	A.R.	7.33	7.54	7.72	7.85	7.94	7.67
4	34	A.R.	7.35	7.55	7.71	7.82	7.93	7.67
5	35	A. R.	7.29	7.53	7.75	7.86	7.91	7.66
6	16	T. C.	7.34	7.60	7.71	7.84	7.95	7.68
7	17	T. C.	7.33	7.57	7.69	7.81	7.97	7.67
8	18	T. C.	7.31	7.60	7.72	7.83	7.95	7.68
9	19	T. C.	7.38	7.62	7.75	7.89	7.98	7.72
10	20	T. C.	7.34	7.63	7.72	7.85	7.92	7.69
Vseh 50 posameznikov Vseh IO posameznikov	rezultati vadbe niso bili večji od 11 %. aritmetične sredine pri uporabnikih niso bile večje od 8 %.							Izpolnjen (FFP2)

Test Zadeva	Dolžina obraza (mm)	Širina obraza (mm)	Globina obraza (mm)	Širina ustja (mm)
	117	155	130	60
2	113	148	128	62
3	112	160	134	59
4	115	148	125	61
5	120	158	132	57
6	118	150	134	59
7	115	152	130	57
8	117	155	134	59
9	114	149	128	57
10	I IO	150	131	55

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7.9.2 PENETRACIJA FILTRSKEGA MATERIALA (EN 149:2001+ Al:2009, točka **8.11)**

Preskusna metoda: Opisana v točki 8.11

PONOVNA OBRAVNAVA			REZULTATI	KOMENTAR
Razvrstitev	Največja penetracija testnega aerosola		Prehod	Podrobnosti glejte v Prilogi ITTA in IITB
	Test NaCl 95 l/min %max	Preskus s parafinskim oljem 95 l/min %max		
FFPI	20	20		
FFP2	6	6		
FFP3				

Priloga IIIA - Rezultat preskusa:

Dobljeni rezultati preskusov so prikazani v naslednjih preglednicah:

Št. vzorca	Stanje	Penetracija natrijevega klorida v skladu s standardom EN 13274-7:2019 Hitrost pretoka 95 l/min	Zahteve v skladu z EN 149:200 I +A1 :2009	Ocena skladnosti/neskladnosti rezultatov preskusa
36	Kot je bilo prejeto	0.86	FFPI S20 %	Sprejeto
37		1.05		
38		0.95		
	Simulirana obdelava z nošenjem	0.99	FFP2 S6 %	Filtrirne polmaske izpolnjujejo zahteve standarda EN 149:200 I +A I :2009, navedene v 7.9.2 v območju prvega in drugega razreda zaščite (FFP I. FFP2)
2		1.01		
3		1.03	FFP3 SI%	
IO	Mehanska trdnost+	0.98		
II	Temperatura	0.96		
12	pogojeno	0.90		

Priloga IDB - Rezultat testa:

Dobljeni rezultati preskusov so prikazani v naslednjih preglednicah:

Št. vzorca	Stanje	Penetracija parafinske oljne meglice v skladu s standardom EN 13274-7:2019 [%] Hitrost pretoka 95 l/min	Zahteve v skladu z EN 149:200 I +A1 :2009	Ocena skladnosti/neskladnosti rezultatov preskusa
39	Kot je bilo prejeto	1.88	FFPI S20 %	Sprejeto
40		2.03		
4]		1.93		
4	Simulirano nošenje zdravljenje	1.95	FFP2S6%	Filtrirne polmaske izpolnjujejo zahteve standarda EN 149:2001+A I :2009 dano v točki 7.9.2 v območju prvega in drugega razreda zaščite (FFP I. FFP2)
5		1.99		
6		1,96		
13	Mehanska trdnost +	1.97	FFP3 SI%	
14	Temperatura	2.01		
15	pogojeno	1.99		

Laboratorij A+ B

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7.10 SODOBNOST S KOŽO (EN 149:2001 + A1 :2009, točka 8.4, 8.5)

Preskusna metoda: Opisano v točkah 8.4 in 8.5.

ZAHTEVA	REZULTATI	KOMENTAR
Za materiale, ki lahko pridejo v stik s kožo uporabnika, ni znano, da bi lahko povzročili draženje ali kakršen koli drug škodljiv učinek na zdravje.	Prehod	Preiskovanci med praktičnim delovanjem in testi TIL niso poročali o draženju ali kakršnem koli drugem škodljivem učinku na zdravje ali občutljivost.

Lab B

7.11 PLAMENOST (EN 149:2001 + Al:2009, točka 8.6)

Preskusna metoda: Opisano v točki 8.6

ZAHTEVA	REZULTATI	KOMENTAR
Uporabljeni material ne sme predstavljati nevarnosti za uporabnika in ne sme biti iz lahko vnetljivega nanosa. Pri preskusu polmaska za filtriranje delcev ne sme goreti ali goreti še 5 s po odstranitvi iz imena.	Prehod	Podrobnosti glejte v Prilogi IV

Priloga IV - Rezultat preskusa: Rezultati preskusa so prikazani v naslednjih tabelah:

Število Samole	Stanje	Vizualni pregled	Zahteve v skladu z EN 149:200 I +Al:2009	Ocena skladnosti/neskladnosti rezultatov preskusa
45	Kot je bilo prejeto	0,0 s	Filtrirna polmaska ne gori ali ne gorijo še več kot 5 s po tem, ko odstranitev iz plamena	Sprejeto Filtriranje polovičnih mask izpolnite zahteve standarda EN 149:2001 + A I :2009 iz točke 7.11
46		0.0 s		
21	Temperaturno pogojeno	0.0 s		
22		0.1 s		

7.12 VSEBINA OGLJIKOVEGA DIOKSIDA V INHALACIJSKEM ALR (EN 149:2001 + Al:2009, klavzula 8.7)

Preskusna metoda: Opisano v točki 8.7

ZAHTEVA	REZULTATI	KOMENTAR
Vsebnost ogljikovega dioksida v vdihanem zraku (mrtvi prostor) v povprečju ne presega 1,0 % (prostorninsko)	Prehod	Podrobnosti glejte v Prilogi V

Priloga V - Rezultat preskusa: Rezultati preskusa so prikazani v naslednjih tabelah:

Št. vzorca	Stanje	vsebnost CO2 v vdihanem zraku zrak [%] po prostornini	Povprečna vsebnost CO2 v vdihan zrak [%] po prostornini	Zahteve v skladu z EN 149:200 I+A I :2009	Ocena skladnosti/neskladnosti rezultatov preskusa
26	Kot je bilo	0.45	0.48	vsebnost CO2 v zrak za vdihavanje ne presega v povprečju 1,0 % do obseg	Sprejeto Filtriranje polovičnih mask zahteve standard EN 149:200 I + Al:2009, navedeno v 7.12
27		0.52			
28		0.47			

Laboratorij B

7.13 GLAVNI VODILNIK (EN 149:2001 + A1 :2009, točka 8.4, 8.5)

Preskusna metoda: Opisano v točki 8.4, 8.5

REQUTREMENT	REZULTATI	KOMENTAR
Trak za glavo je zasnovan tako, da je mogoče polmasko, ki filtrira delce, enostavno natakniti in sneti.	Prehod	Med praktičnim preskusom delovanja ni bilo težav s pasovi za glavo, ki so jih uporabnice ponovno uporabile.
Trak za glavo mora biti nastavljiv ali samonastavljiv in dovolj trden, da polmasko za filtriranje delcev trdno drži v položaju in da lahko ali ohranja skupne zahteve glede uhajanja navznoter za napravo;;	Prehod	Uporabniki med praktičnim preskusom delovanja niso poročali o težavah z naglavnim pasom.

Laboratorij B

7.14 FJELD VIDIKA (EN 149:2001 + A1 :2009, točka 8.4)

Preskusna metoda: Opisano v točki 8.4

ZAHTEVA	REZULTATI	KOMENTAR
Vidno polje je sprejemljivo, če je tako določeno pri praktičnih preskusih delovanja.	Prehod	Po praktičnih preskusih delovanja ni bilo negativnih pripomb.

LabB

7.15 IZVODNI VENTIL (EN 149:2001 + Al :2009 člen 8.2, 8.3.4, 8.8, 8.9.1)

Preskusna metoda: Klavzula 8.2. 8.3.4. 8.8. 8.9.1

R.EOUIREMENT	REZULTATI	KOMENTAR
Polmaska s filtriranjem delcev ima lahko enega ali več ventilov za izdihovanje, ki morajo pravilno delovati pri vse usmeritve.	*NIA*	V testiranih vzorcih ni bilo ventila za izdihavanje.
Če je predviden izpihovalni ventil, mora biti zaščiten pred di11 in mehanskimi poškodbami ali odporen nanje in je lahko zakrit ali vključuje katero koli drugo napravo, ki je lahko potrebna za polmasko za filtriranje delcev, da se zagotovi skladnost s členom 7.9	*NIA*	V testiranih vzorcih ni bilo ventila za izdihavanje.
Ventil(-i) za izdih, če je(so) vgrajen(-i), mora(-jo) še naprej pravilno deluje po neprekinjenem izdihu s pretokom 300 I/min v obdobju 30 s.	*NIA*	V testiranih vzorcih ni bilo ventila za izdihavanje.
Ko je ohišje izdihovalnega ventila pritrjeno na mora vzdržati natezno silo I ON, ki se uporablja za I Os.	*NIA*	V testiranih vzorcih ni bilo ventila za izdihavanje.

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7.16 ODPORNOST PROTI DIHANJU (EN 149:2001 +AI :2009, točka 8.9)

Preskusna metoda: Opisano v točki 8.9

REOUTREMENT	REZULTATI	KOMENTAR
<table><tr><td rowspan="2">Razvrstitev</td><td colspan="3">Ma't oermitted resistance 'mbar)</td></tr><tr><td colspan="2">fnhalacija</td><td>Izdih</td></tr><tr><td></td><td>30 I/min</td><td>95 I/min</td><td>160 I/min</td></tr><tr><td>FFPI</td><td>0.6</td><td>2.1</td><td>3.0</td></tr><tr><td>FFP2</td><td>0.7</td><td>2.4</td><td>3.0</td></tr><tr><td>FFP3</td><td>1.0</td><td>3.0</td><td>3.0</td></tr></table>	Prehod	Podrobnosti glejte v Prilogi VIA-VIB

Priloga VIA - Rezultat testa:
Dobljeni rezultati preskusov so prikazani v naslednjih preglednicah:

Odpornost na vdihavanje

Št. vzorca	Stanje	Odpornost pri vdihavanju (mbar)				
		Stopnja pretoka 30 I/min [mbar]	Zahteve v skladu z EN 149:200 I +A I :2009	Stopnja pretoka 95 I/min [mbar]	Zahteve v skladu z EN I 49:2001+A 1 :2009	Ocena skladnosti/neskladnosti rezultatov preskusa
42	Kot je bilo prejeto	0,50	FFPI S 0,60 FFP2 S 0,70 FFP3 S 1.0	1.34	FFPI S 2.10 FFP2 S 2.40 FFP3 S 3,00	Sprejeto izpolnjuje pogoje za FFPI. FFP2. FFP3
43		0,53		1.37		
44		0.49		1.37		
7	Simulirana obdelava z nošenjem	0.52		1.40		
8		0.50		1.39		
9 .,		0.51		1.41		
?♦	Temperaturno pogojeno	0.49		1.36		
24		0.50		1.38		
25		0.49		1.37		

Odpornost pri izdihu

Št. vzorca	Stanje	Stopnja pretoka	Neposredno obrnjeni	obrnjeni navpično navzgor	obrnjeno navpično navzdol	Leži na levi strani	Leži na desni strani	Zahteve v skladu s standardom EN 149:200l+Al :2009	Ocena skladnosti/neskladnosti rezultatov preskusa
42	Kot je bilo	1601/min	1.65	1.69	1.71	1.72	1.74	FFPI S 3.0 FFP2 S 3.0 FFP3 S 3.0	Sprejeto Kvalificira se FFPl. FFP2. FFP3
43			1.71	1.71	1.72	1.75	1.78		
44			1.69	1.67	1.70	1.71	1.72		
7	Simulirano nošenje zdravljenje		1.63	1.68	1.69	1.70	1.75		
8			1.68	1.70	1.73	1.74	1.78		
9.			1.65	1.72	1.76	1.71	1.73		
?♦	Temperatura pogojeno		1.60	1.64	1.68	1.70	1.72		
24			1.58	1.65	1.63	1.69	1.73		
25			1.56	1.62	1.65	1.64	1.68		

Laboratorij A

UNIVERZA

LNA

POTRDILO

7.17 OZIROMA (EN 149:2001 + Al:2009, točka 8.9, 8.10)

Preskusna metoda: Opisano v točki 8.8, 8.10

REOUTREMENT	REZULTATI	KOMENTAR
Polmaske z ventilom za filtriranje delcev: Po zamašitvi upori pri vdihavanju ne smejo presegati: FFPI :4mbar. FFP2:5mbar. FFP3: 7mbar pri neprekinjenem pretoku 95 L/min. Upor pri izdihu ne sme presegati 3mbar pri neprekinjenem pretoku 160L/min. Polmaske brez ventila za filtriranje delcev: Po zamašitvi upori pri vdihavanju ne smejo presegati: FFPI :3mbar. FFP2:4mbar. FFP3: 5mbar pri neprekinjenem pretoku 95 L/min	NAs	To je neobvezen preskus, ki ga stranka ne želi.

Laboratorij -

7.18 ODSTRANJIVI DELI (EN 149:2001 + Al:2009, klavzula 8.2)

Preskusna metoda: Opisano v točki 8.2

REOUTREMENT	REZULTATI	KOMENTAR
Vsi razstavljivi deli (če so vgrajeni) se zlahka povežejo in pritrdijo. po možnosti ročno	*NIA*	Ni odstranljivega dela.

Laboratorij -

Prehod	*Reauirement zadovoljen.*
NCR	*Zahteva ni izpolnjena. Za več informacij glejte razdelek "Podrobnosti o rezultatu".*
NAs	*Ocena ni bila izvedena.*
NIA	*Reauirement not ann/icable.*

LABORATORIJSKE INFORMACIJE

Koda	Ime laboratorija	Kompetence Razlage
Laboratorij A	UNIVERSAL SERTIFIKASYON VE GOZETIM HIZMETLERI TIC. LTD. STI.	Notranje laboratorijske storitve priglašenega organa
LabB	GCNTR ULUSLARARASI BELGELENDIRME, GOZETIM, EGITIM VE DIS TICARET LIMITED SIRKETI KOCAELI DILOVA SUBESI	Laboratorij ima akreditacijo Turške akreditacijske agencije s številko AB-1252-T v skladu s standardom EN ISO/IEC 17025:2017.

- Laboratoriji so pogodbeni organi z UNIVERSAL CERTIFICATION, njihovo tehnično usposobljenost pa nadzira/ocenjuje UNIVERSAL CERTIFICATION na podlagi določb standarda EN ISO/IEC 17065 Zahteve za organe, ki certificirajo izdelke, postopke in storitve.
- Vsak rezultat preskusa, naveden v tem poročilu o preskusu, je prikazan z oznako laboratorija, ki ga je izdal.

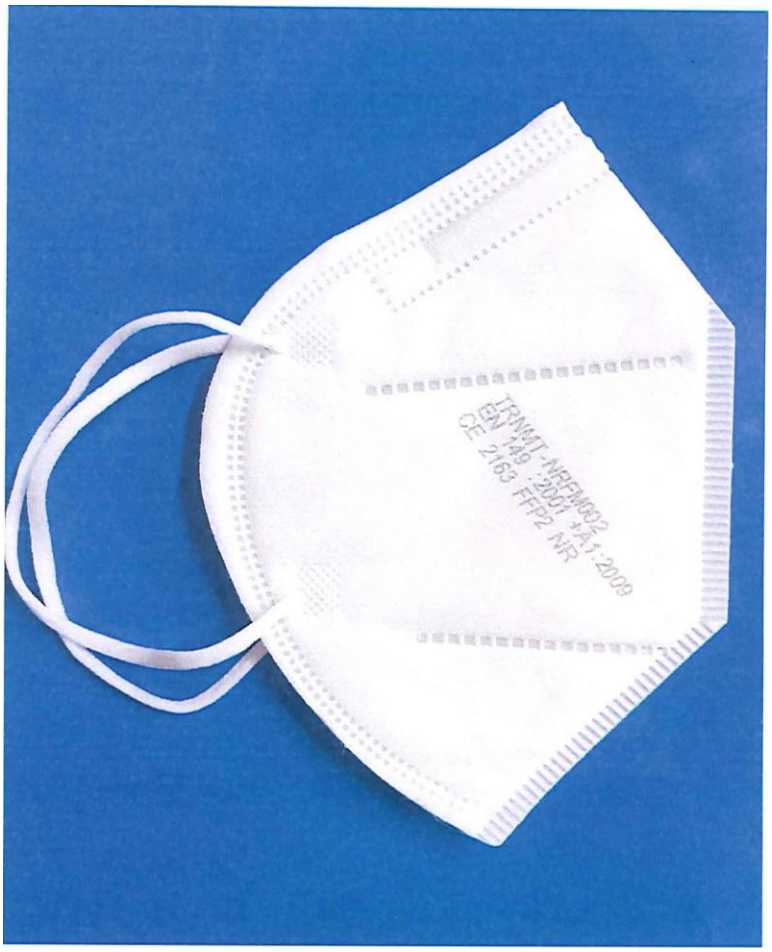
VERS-A+

L SERTIFIKASYOM VE GOZETIM HiZiVI. TIC. LTD. $Tl.

Fazil Bulvan, Keyap Sitesi, E2 Blok, No:44/Bt:a.,e Yukan Dudullu-Omraniye/ISTANBUL

Telefona: 0216 455 80 80 Faks: 0216 455 80 08

Sam pic Foto



- Konec poročila -

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