UNIVERSAL CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-752/R1

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

TULPAR SAĞLIK ÜRÜNLERİ İMALAT SAN.VE LTD. ŞTİ.

Konutkent mah. 3035 Cadde No:74/B28 Çankaya, Ankara TURKEY

by the following manufacturer

Ece Dermokozmetik Ltd. Şti.

Tevfikbey Mah. Şehit Erol Olçok Cad. No:19 İç Kapı No:1 Küçükçekmece, 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(18 January 2021 Revision 01)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, 6 layered, with valve, head straps and adjustable nose bar.

Brand Name: DNA **Model:** 2934V
Classification: FFP3 NR

For more details, refer technical evaluation report provided to the manufacturer, dated 29.05.2021 and number 2163-KKD-752-R1.

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

This certificate is initially issued on **17/06/2021** and updated on **29/05/2021** will be valid for 5 years from the issue date, 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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NB 2163

CONFORMITY TO TYPE CERTIFICATE

Certificate No: 2163-PPE-752/01

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

TULPAR SAĞLIK ÜRÜNLERİ İMALAT SAN.VE LTD. ŞTİ.

Konutkent mah. 3035 Cadde No:74/B28 Çankaya, Ankara TURKEY

by the following manufacturer

Ece Dermokozmetik Ltd. Şti.

Tevfikbey Mah. Şehit Erol Olçok Cad. No:19 İç Kapı No:1 Küçükçekmece, İstanbul TURKEY

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 Nr.	Date	Issuing NB Nr.
DNA / 2934V	FFP3 NR	2163-PPE-752/R1	29.05.2021	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 **29/05/2021** and will be valid for one year, until **28/05/2022** 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

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 29.05.2021 / 2163-KKD-752-R1

Initial Report Date / NO: 17.06.2020 / 2163-KKD-752

This technical assessment report is enriched and updated due to changes of the mask design and applicant has signed a sub-contract with the manufacturer. The manufacturer is updated the technical file regarding the new design of the product.

Applicant: Tulpar Sağlık Ürünleri İmalat San.ve Ltd. Şti.

Address: Konutkent mah. 3035 Cadde No:74/B28 Çankaya, Ankara TURKEY

Manufacturer: *Ece Dermokozmetik Limited Şti.*

Address: *Tevfikbey Mah.Şehit Erol Olçok Cad.No:19 İç Kapı No:1 Küçükçekmece, İstanbul TURKEY*

Introduction

This report is for the, given above, manufacturer prepared according to the test results obtained from Universal Certification Conformity Assessment Co., dated 30.04.2021 with Serial Id *04-2021-T0853* based on EN 149: 2001 + A1: 2009 standard and the technical file dated *18 January 2021 (Revision 01)* 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 2163-PPE-752/R1 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.

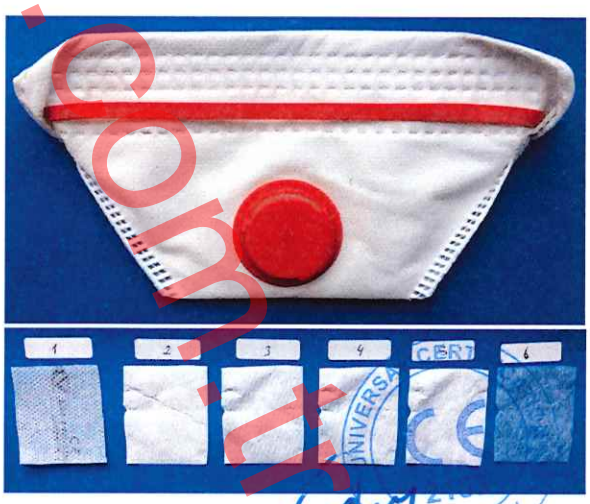
Product Description: Single use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 6 layered, with valve, head straps and adjustable nose bar.

Component and Materials:

Component	Material	Grade
Outer Layer	Spunbond fabric	60 g/m²
Filter Layer I	Melt-blown fabric	20 g/m²
Filter Layer II	Melt-blown fabric	20 g/m²
Filter Layer III	Melt-blown fabric	20 g/m²
Filter Layer IV	Melt-blown fabric	20 g/m²
Inner Layer	Spunbond fabric	20 g/m²
Head Strap	TPE Elastan	55 cm
Nose Bridge	Aluminum	10 cm
Valve	Plastic	Diameter:30 mm Depth:5 mm

Classification: FFP3 NR

Brand Name: DNA **Model:** 2934V



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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 prossible 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 **FFP3** 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. Details given in Annex 1 of Technical File.
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. Manufacturer declares that the material do not have any adverse effect for the wearers health in Section 5 of the Technical File. 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 5%, the values varies between 0,48% and 2,79%. 9 of the 10 individual's arithmetic mean is smaller or equal to 2%, the values varies between 1,08% and 2,15%. **According to the reported results, the product meets the limits for FFP1, FFP2, FFP3 classifications.**
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	0,50		Filtering half masks fulfill the requirements of the standard EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2 and FFP3** classes.
(A.R.)	37	0,48		
(A.R.)	38	0,39	FFP1 ≤ 20 %	
(S.W.)	1	0,64		
(S.W.)	2	0,59	FFP2 ≤ 6 %	
(S.W.)	3	0,58		
(M.S. T.C.)	10	0,38	FFP3 ≤ 1 %	
(M.S. T.C.)	11	0,36		
(M.S. T.C.)	12	0,34		

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	0,15	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2 and FFP3** classes.
(A.R.)	40	0,34		
(A.R.)	41	0,49		
(S.W.)	4	0,78		
(S.W.)	5	0,77		
(S.W.)	6	0,76		
(M.S. T.C.)	13	0,70		
(M.S. T.C.)	14	0,72		
(M.S. T.C.)	15	0,69		

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 0.0s		

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	0,47	0,47 [%]	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	0,48			
(A.R.)	28	0,45			

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 valve on the mask was functioning tested during the visual inspection. Total 12 valves sample(3 as received, 3 after temperature conditioning and 3 after the test for simulated wearing and 3 after the flow conditioning) tested and the results are valid for FFP1, FFP2 and FFP3 protection classes.
The samples tested in accordance to 7.9 were functional those subjected to temperature, mechanical and flow conditioned processes.
No problem with the functionality of the valves noted while subjected to 300 L/min for 30 second.
The valve tested withstands to a 10 N force applied to the valve to the horizontally.

Passed.

Article 7.16

Breathing Resistance: Inhalation

The overall evaluation in the figures gathered for 12 different samples 3 as received, 3 with temparature conditioning, 3 simulated wearing treatment and 3 flow 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 Annex 1 on the technical file. The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing 2934V. The mask marking indicates that the mask will carry information about the brandname (DNA) 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 2934V drawing exists in the technical file Section 5 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 found to be appropriate Section 4, 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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NIVERSAL CERTIFICATION CONFORMITY ASSESSMENT CO.
Tatlisu Mah. Arif Ay Sk. No:16/3 Umraniye, Istanbul / TURKEY

TEST REPORT

Report Date:30.04.2021
Report Number:04-2021-T0853

CLIENT and SAMPLE INFORMATION

TEST OWNER	TULPAR SAĞLIK ÜRÜNLERİ İMALAT SAN.VE LTD.ŞTİ		
ADDRESS	Konutkent mah. 3035 Cadde No:74/B28 Çankaya ,Ankara		
SAMPLE DESCRIPTION	Duck type protective mask-C2		
BRAND NAME – MODEL	DNA 2934 V /FFP3		
CASE NUMBER	CE-PPE-3845		
SAMPLE RECEIVE DATE	20.04.2021		
STARTING DATE	21.04.2021		
FINISH DATE	29.04.2021		
NUMBER OF SAMPLES	52	SAMPLE IDs:	1 – 52
AS RECEIVED SAMPLE NO	26-46, 50		
CONDITIONING SAMPLE NO	Simulated Wearing Treatment	1-2-3-4-5-6-7-8-9 (As Received)	
	Temperature Conditioning (T.C.)	10-11-12-13-14-15 (Sample after test of Mechanical Strength)	
		16-17-18-19-20-21-22-23-24-25-51 (As Received)	
	Mechanical Strength	10-11-12-13-14-15-52 (As Received)	
	Flow Conditioning (Only for particle filtering half masks with valve.)	47 (As Received) 48-49 (Sample after test of Temperature conditioning)	

NOTE 1

The results given in this test report belongs to the samples tested. The report content cannot be recreated partially without the written consent of UNIVERSAL CERTIFICATION.

NOTE 2

Requirements are taken from the EN 149: 2001 + A1: 2009 standard and the evaluation of results carried out according to these requirements.

NOTE 3

Information about conditioning;

Simulated wearing treatment:

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask is mounted on a Sheffield dummy head. For testing, a saturator was incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 ºC to allow for the cooling of the air before it reaches the mouth of the dummy head. The air saturated at (37 ±2) ºC at the mouth of the dummy head.
In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head inclined so that the water runs away from the mouth and is collected in a trap.
The breathing machine is brought into operation, the saturator switched on and the apparatus allowed to stabilize. The particle filtering half mask under the mounted on the dummy head. During the test time at approximately 20 min intervals the particle filtering half mask completely removed from the dummy head and refitted such that during the test period it is period it is fitted ten times to the dummy head.

Temperature conditioning (T.C.):

Exposed the particle filtering half masks to the following thermal cycle:

a) *For 24 h to dry atmosphere of (70±3) ºC;*
b) *For 24 h to dry atmosphere of (-30±3) ºC;*

And allowed to return room temperature for at least 4 h between exposures and prior to subsequent testing.
The conditioning carried out in a manner which ensured that no thermal shock occurs.

Mechanical strength:

After the masks / strainers are removed from their packaging (if they have seals on them, they are not opened) they are placed in the wide channels on the upper table of the device horizontally and not touching each other.

The device set and operated to operate at 100 revolutions per minute and the conditioning time to be 20 minutes.

As a result of the experiment, it was checked that any deterioration in the masks / strainers or the disassembled parts have not loosened or separated in any way.

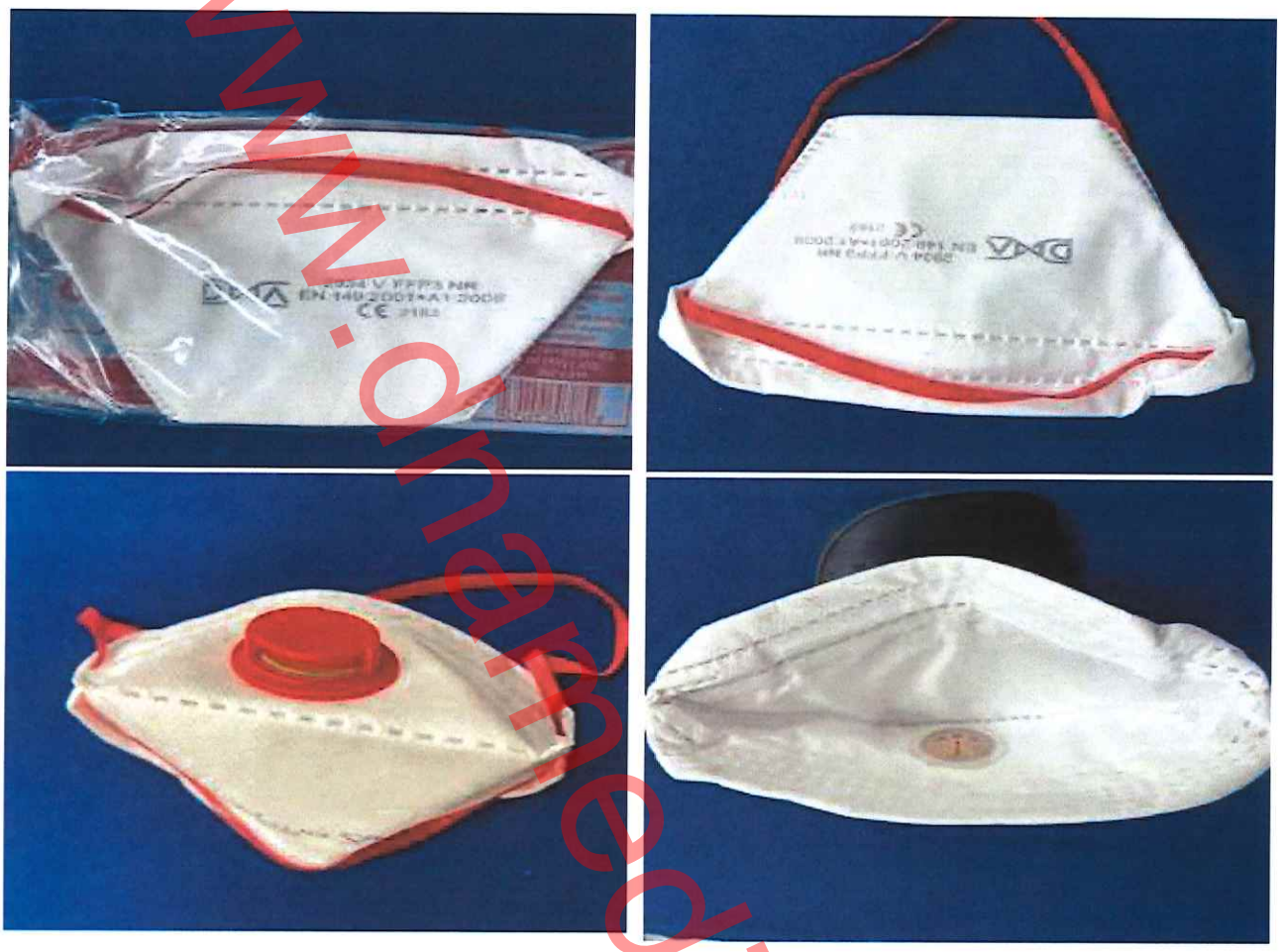
Flow conditioning:

A total of 3 valved particle filtering half masks tested , one as received and two temperature conditioned in accordance with temperature.

NOTE 4

Information about evaluation;

Passed	*Results are suitable to requirements.*
Failed	*Results are not suitable to requirements.*
N/A	*Results are not applicable to requirements.*



TEST RESULTS, REQUIREMENTS and EVALUATION

7.4 PACKAGING

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
The masks were packaged in sealed inside original box that gave some protection against mechanical damage or contamination before use.	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.	Passed

7.5 MATERIAL

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
Materials used are suitable to withstand handling and wear during the limited laboratory testing carried out.	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.	Passed
It did not constitute a hazard or nuisance for the wearer.	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Passed
None of specimens conditioned suffered mechanical failure.	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.	Passed
None of the specimens did not collapse after conditioning.	When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Passed

7.6 CLEANING AND DISINFECTING

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
This analysis is not applicable because the masks are single use.	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

7.7 PRACTICAL PERFORMANCE

Test Method: EN 149:2001 + A1:2009

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

Number of sample : 29 (A.R)[1], 30 (A.R)

ASSESSED ELEMENTS	POSITIVE ASSESSMENT	NEGATIVE ASSESSMENT	RESULTS	REQUIREMENTS	EVALUATION
The face piece fitting Head harness comfort Security of fastenings Field of vision	2 2 2 2	0 0 0 0	No imperfections.	Filtering half masks should not have imperfections related to wearer's acceptance.	Passed

[1]: *As received*

7.8 FINISH OF PARTS

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
None of the specimens used in laboratory have no sharp edges or burrs.	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Passed

7.9.1 TOTAL INWARD LEAKAGE

Test Method: EN 149:2001 + A1:2009

REQUIREMENTS	EVALUATION
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	Qualifies FFP3

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

TEST SUBJECT	NO OF SAMPLE	CONDITION	1. WALK (%)	HEAD SIDE/ SIDE (%)	HEAD UP/DOWN (%)	TALK (%)	2. WALK (%)	AVERAGE (%)
Z.Y	31	A.R.	1,32	2,38	2,79	1,28	2,03	1,96
K.D	32	A.R.	0,48	1,53	0,84	1,19	1,37	1,08
Y.A	33	A.R.	2,06	0,81	1,23	2,25	2,43	1,76
S.G	34	A.R.	2,83	1,65	1,28	1,42	2,05	1,85
U.A	35	A.R.	2,03	2,51	2,08	2,16	1,07	1,97
C.Y	16	T.C.	2,51	2,73	2,44	2,53	0,54	**2,15**
F.D	17	T.C.	1,32	2,19	1,38	2,07	1,93	1,78
E.C	18	T.C.	1,65	1,88	1,94	1,76	1,98	1,84
U.E	19	T.C.	2,77	1,79	1,74	1,81	1,77	1,98
C.A	20	T.C.	2,38	1,62	1,85	2,04	1,84	1,95

All of the 50 individual exercise results were not greater than 5%
9 of the 10 individual wearer arithmetic means were greater than 2 %

The information in the test subject column is the initial of the candidates who performed the test.

***1.Walk**: walking for 2 min without head movement or talking;*

***Head side/side:** walking turning head from side to side (approximately 15 times), as if inspecting the walls of a tunnel for 2 min;*

***Head up/down:** walking and moving head up and down (approximately 15 times), as if inspecting the ceiling and floor for 2 min;*

***Talk:** walking and reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min;*
***2.Walk:**: walking for 2 min without head movement or talking*

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Test Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
S.G	127	135	125	65
Y.A	115	137	127	65
U.A	145	143	140	60
K.D	125	135	130	55
Z.Y	130	140	135	55
E.C	131	135	136	60
F.D	115	145	135	61
U.E	120	160	140	60
C.Y	123	145	125	63
C.A	125	160	145	65

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7.9.2 PENETRATION OF FILTER MATERIAL

Test Method: EN 149:2001 + A1:2009

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

NO. OF SAMPLE	CONDITION	RESULTS Penetration of **Sodium Chloride** in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	REQUIREMENTS	EVALUATION
36	As received	0,50	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Qualifies FFP1, FFP2,FFP3
37		0,48		
38		0,39		
1	Simulated wearing treatment	0,64		
2		0,59		
3		0,58		
10	Mechanical strength + Temperature conditioned	0,38		
11		0,36		
12		0,34		

Results for samples 10,11 and 12 is taken by exposure test. (the mask is loaded 120mg of NaCl)

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

NO. OF SAMPLE	CONDITION	RESULTS Penetration of **Paraffin Oil** Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	REQUIREMENTS	EVALUATION
39	As received	0,15	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Qualifies FFP1, FFP2,FFP3
40		0,34		
41		0,49		
4	Simulated wearing treatment	0,78		
5		0,77		
6		0,76		
13	Mechanical strength + Temperature conditioned	0,70		
14		0,72		
15		0,69		

Results for samples 13,14 and 15 is taken by exposure test. (the mask is loaded 120mg of Paraffin Oil)

7.10 COMPATIBILITY WITH SKIN

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
No irritation or any other adverse effect to health or sensitivity reported by the subjects during the practical performance and TIL tests.	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.	Passed

7.11 FLAMMABILITY

Test Method: EN 149:2001 + A1:2009

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

NO. OF SAMPLE	CONDITION	VISUAL INSPECTION/ TIME (s)	REQUIREMENTS	EVALUATION
45	As received	0 s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame.	Passed
46		0 s		
21	Temperature conditioned	0 s		
22		0 s		

7.12 CARBON DIOXIDE CONTENT OF THE INHALATION AIR

Test Method: EN 149:2001 + A1:2009

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

NO. OF SAMPLE	CONDITION	RESULTS CO_2 Content Of The Inhalation Air [%] By Volume	RESULTS An Average CO_2 Content Of The Inhalation Air [%] By Volume	REQUIREMENTS	EVALUATION
26	As received	0,47	0,47	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume.	Passed
27		0,48			
28		0,45			

7.13 HEAD HARNESS

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
There is no problem with the head harness reported by the wearers during the practical performance test.	The head harness shall be designed so that the particle filtering half-mask can be donned and removed easily.	Passed
There is 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.	Passed

7.14 FIELD OF VISION

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
There were no adverse comments following practical performance tests.	The field of vision is acceptable if determined so in practical performance tests.	Passed

7.15 EXHALATION VALVE

Test Method: EN 149:2001 + A1:2009

RESULTS	REQUIREMENTS	EVALUATION
Samples has one exhalation valve, which shall function correctly in all orientations.	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Passed
The samples protect the valve from dirt and mechanical damage.	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	Passed
Exhalation valves are used correctly after continuous exhalation of 300 l/min for a period of 30 seconds.	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30s.	Passed
Valves withstanded axially a tensile force of 10N applied for 10s.	When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10s.	Passed

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7.16 BREATHING RESISTANCE

Test Method: EN 149:2001 + A1:2009

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

Inhalation Resistance

NO. OF SAMPLE	CONDITION	FLOW RATE 30 l/min [mbar]	REQUIREMENTS	FLOW RATE 95 l/min [mbar]	REQUIREMENTS	EVALUATION
42	As received	0,50	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	1,76	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed Qualifies FFP1,FFP2, FFP3
43		0,51		1,78		
44		0,52		1,81		
7	Simulated wearing treatment	0,48		1,82		
8		0,47		1,84		
9		0,50		1,75		
23	Temperature conditioned	0,48		1,70		
24		0,48		1,46		
25		0,46		1,56		
47	Flow conditioned	0,45		1,54		
48		0,49		1,67		
49		0,46		1,83		

Exhalation Resistance

NO. OF SAMPLE	CONDITION	FLOW RATE	Facing directly [mbar]	Facing vertically upwards [mbar]	Facing vertically downwards [mbar]	Lying on the left side [mbar]	Lying on the right side [mbar]	REQUIREMENTS	EVALUATION
42	As received	160 l/min	1,75	1,72	1,72	1,68	1,69	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed Qualifies FFP1,FFP2, FFP3
43			1,52	1,52	1,50	1,49	1,48		
44			1,85	1,84	1,82	1,79	1,79		
7	Simulated wearing treatment		1,80	1,82	1,81	1,81	1,75		
8			1,78	1,77	1,79	1,77	1,74		
9			1,69	1,70	1,71	1,70	1,70		
23	Temperature conditioned		1,66	1,67	1,63	1,64	1,64		
24			1,51	1,50	1,54	1,52	1,50		
25			1,48	1,42	1,43	1,45	1,44		
47	Flow conditioned		1,47	1,40	1,45	1,46	1,44		
48			1,49	1,44	1,48	1,51	1,48		
49			1,46	1,42	1,44	1,48	1,43		

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7.18 DEMOUNTABLE PARTS

Test Method: EN 149:2001 + A1:2009

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

-End of Report-

TEST REVIEW

MURAT AYDEMİR

APPROVAL

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