

DICHIARAZIONE UE DI CONFORMITA'

Nome e indirizzo del fabbricante:

ROTOFORM Srl – via Ardeatina km 20,400 (via dei Tamarindi, 14) – 00134 Roma

Tel. 06.71300197 – fax 06.71300197 – email: info@rotoform.it

P.IVA 02111231003 – C.F. 08653830581

Dichiara sotto la propria responsabilità che il Dispositivo di Protezione Individuale di seguito descritto:

- **Modello: 501 FFP2 NR D – Elastici auricolari taglia regular**
- **Modello: 501 FFP2 NR D – Elastici auricolari taglia small**
- **Modello: 501 FFP2 NR D – Elastici nicali taglia regular**
- **Modello: 501 FFP2 NR D – Elastici nicali taglia small**

È conforme alle disposizioni:

- Regolamento (UE) 2016/425
- Norma armonizzata EN 149:2001 + A1:2009

Ente notificato: **GEPTESZT KFT (PPE Notified Body n° 2233)**

Jablonka u.79

1037 Budapest – Ungheria

Ha eseguito l'esame EU del tipo (Modulo B) ed è garantito dal certificato EU del tipo:

No. TD11/GT285-X3/554/2302/EN/2233

Il DPI è soggetto alla seguente procedura di valutazione della conformità:

La conformità al tipo basata sul controllo interno della produzione unito a prove del prodotto sotto controllo ufficiale effettuate a intervalli casuali (modulo C2) dell'organismo notificato:

GEPTESZT KFT. (No 2233)

Roma, 10/02/2023

L'Amministratore unico - Di Virgilio Tullio


Rotoform s.r.l.
Via dei Tamarindi 14 - 00134 Roma
Tel. 06.71300197 - Fax 06.71302974
P.Iva 02111231003



Rotoform s.r.l.

Sede e Stabilimento:

00134 Roma (S. Palomba)

Via dei Tamarindi, 14

(già Via Ardeatina km. 20,400)

Tel. 06.71.30.01.97 - Fax 06.71.30.29.74

www.rotoform.it - info@rotoform.it

Cap. Soc. € 98.800,00 i.v. · P. IVA 02111231003 · Cod. Fisc. 08653830581 · C.C.I.A.A. 671019 · Iscr. Trib. 870/89



Il marchio della
gestione forestale
responsabile

MODULE B - EU TYPE-EXAMINATION CERTIFICATE EXTENSION

The PPE type complies with the applicable essential health and safety requirements of Regulation (EU) 2016/425.

*Present EU type-examination certificate is valid only with**

Document No: TD11/GT285-X3/554/2302/EN/2233

Category: III - Personal protective equipment providing respiratory system protection

Designation: Particle filtering half mask

Model: 501 FFP2 NR D

Classification: FFP2 NR D

Description: FFP2 NR D non reusable particle filtering half mask without valves in white colour, normal size with head band or ear loop and dolomite performance.
FFP2 NR D non reusable particle filtering half mask without valves in white colour, small size with head band or ear loop and dolomite performance.

Applicant: ROTOFORM SRL
Via Ardeatina, Km. 20, 400 (Via Dei Tamarindi, 14) 00134 Roma, Italy

Reference of applied standard(s) / other technical specification(s):

EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles.

Test report / document reference(s):

*VD35/285/2104/E/2233 & TD11/GT285/312/2104/E/2233

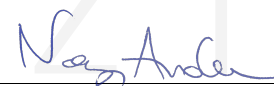
VD36/GT285-X3/2023/EN

The certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in point (c) of Article 19. of Regulation (EU) 2016/425.

Date of issue: Budapest, HUN - 10/02/2023

Date of expiry: 29/04/2026

GÉPTESZT Kft.
EVE Tanúsító Szervezet
NB 2233
1037 Budapest, Jablonka u.79.



Andrea Nagy
Certification manager

Marking and instructions have been assessed in the English language only. It is the Manufacturer's/Authorised Representative's responsibility to obtain and supply language versions acceptable to the country where the product is to be sold.

The EU type-examination certificate remains the property of GÉPTESZT Kft. and will be withdrawn in case of existence of conditions stated in Article 32 point 5 and in Annex V. point 7.7 of Regulation (EU) 2016/425 of the European Parliament of the Council.

The manufacturer shall inform the notified body of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. (Annex V. point 7.2 of Regulation (EU) 2016/425)

Legal remedy can be applied against the condition stated in the EU type-examination certificate. The application for appeal should be submitted to the Director Manager of GÉPTESZT Kft. and the application will be judged by the board of GÉPTESZT Kft. Certificate Body.

MODULE C2 CERTIFICATE

of conformity to type assessment based on internal production control plus supervised product checks at random intervals (module C2)

ED29/111/2302/P114

Manufacturer: **ROTOFORM SRL**
Address: Via Ardeatina, Km. 20, 400 (Via Dei Tamarindi, 14) 00134 Roma, Italy
Place of inspection: Via Ardeatina, Km. 20, 400 (Via Dei Tamarindi, 14) 00134 Roma, Italy
Date of inspection: 25 January, 2023

The above mentioned company is authorized to affix marking

CE 2233

on the personal protective equipment(s) listed in Annex 1 of the certificate

Type of inspection: module C2

The results of control are covered by the EU type-examination certificate(s) listed in Annex 1 of the certificate.

GÉPTESZT KFT.
EVE Ellenőrző Szervezet
NB 2233
1037 Budapest, Jablonka u. 79.

Date of issue: 09.02.2023
Date of expiry: 31.12.2023


Lajos Tóth
Inspection manager

Method used during inspection: On-site production control according to regulation 2016/425 module C2 and relevant RfU sheets. Supervised product checks according to the harmonised standards.

Requirement: Fulfilment of Article 19 c.) i. point of the regulation 2016/425 EU in accordance with Annex VII, module C2 conformity to type assessment.

MODULE C2 CERTIFICATE

Annex 1 of the certificate: ED29/111/2302/P114

The list of PPE is provided by the manufacturer on his own responsibility.

List of PPEs:

Model	Description	EU type-examination certificate	Issued by
501 FFP2 NR	Particle filtering half mask	TD11/GT285/312/2104/E/2233	Gépteszt
501 FFP2 NR	Particle filtering half mask	TD11/GT285/312/2104/X1/E/2233	Gépteszt
501 FFP2 NR	Particle filtering half mask	TD11/GT285/312/2104/X2/E/2233	Gépteszt
501 FFP2 NR	Particle filtering half mask	TD11/GT285-X3/554/2302/EN/2233	Gépteszt

G É P T E S Z T

GÉPTESZT Kft.
Notified Body No. 2233
registered in the European Union

Address: Jablonka St. 79., Budapest, 1037, HUNGARY
e-mail: nb2233@gepteszt.hu
web: www.gepteszt.hu
Phone: +3612503531



PERSONAL PROTECTIVE EQUIPMENT PRODUCT CHECK ROUTINE TEST REPORT

EN 149:2001+A1:2009
Particle filtering half mask

The examination and testing of Personal Protective Equipment were carried out in accordance with
MSZ EN ISO/IEC 17025:2018 standard
by GÉPTESZT Kft. Notified Body, identified under number 2233 in the EU

Customer: Rotoform srl
Address: Via Ardeatina, km. 20, 400 (Via dei Tamarindi, 14)

Model: 501 FFP2 NR

Classification: FFP2 NR D

Exhalation valve: no

Inhalation valve: no

Uses: non reusable (NR)

Project number: GT285

Test report number: VD36/GT285-X3/2023/EN

Project worksheet number: VD34/2023/GT285-X3

Date of the test: 31. 01.- 10. 02. 2023.

Samples received date: 30.01.2023. and 02.02.2023.

Sample numbers: 1 - 51

Attachment: no

Issued: Budapest, 10.02.2023.

GÉPTESZT KFT.
EVE Vizsgáló Laboratórium
NB 2233
1037 Budapest, Jablonka u. 79.
Labor: 1032 Budapest, Gyenes u.12.

Budai Dániel
Director of Laboratory



Relevant standards, directives and requirements:

EN 149:2001+A1:2009 Filtering half masks to protect against particles

Description of the sample

The manufacturer will add the next versions to the mask. The layer structure has not changed:

The foldable mask contains these components (ami nem kell, kihúzni):

- normal size with head band, white colour + dolomite performance
- small size with ear loop, white colour + dolomite performance
- small size with head band, white colour + dolomite performance

COMPONENT OR SUB-COMPONENT	MATERIAL
Nose Bar	Double wire PP material
Ear Loop	28% Spandex 72% Polyester yarn
Waterproof fabric (external Layer)	Non-woven cloth fabric White and colors
FILTER_ 2 nd Layer	Non-woven cloth fabric
Melt blown cloth filter layer 2 x filtering layers	Ultra fine polypropylene filter cloth
FILTER_ 4 nd Layer	Non-woven cloth fabric
Skin care fabric (internal Layer)	Non-woven cloth fabric

Short description of routine tests:

Requirement	Test method	Description	Result
7.9.1	8.5	Total inward leakage	Passed
7.9.2	8.11	Penetration of filter material: paraffin oil	Passed
7.12	8.7	Carbon dioxide content of the inhalation air	Passed
7.16	8.9	Breathing resistance	Passed
7.17	8.10	Clogging	NA



Analysis and details of routine test results:

The samples were subjected to the mechanical strength test and thermal conditioning without package.

NORMAL SIZE WITH HEAD BAND, WHITE COLOUR + DOLOMITE PERFORMANCE





7.9.1 Total inward leakage

With sodium chloride aerosol. The masks were in good condition.

Number of subjects were replaced, because of not fitting/facial dimensions:0.....

Subjects facial dimensions				
Subject	Face length, mm	Face width, mm	Face depth, mm	Mouth width, mm
NA	115	100	125	50
TLI	125	165	140	75
KD	160	120	110	53
BP	120	125	116	57
RE	115	138	112	48
BD	120	130	135	55
MM	113	138	123	63
VBA	110	115	115	55
KL	120	140	140	60
LA	123	140	105	60

Subject	Sample	Cond.	Total inward leakage, %					Mean, %
			Walk	Head left/right	Head up/down	Talk	Walk	
NA	1	A.R.	4,14	4,70	4,34	8,74	3,94	5,17
TLI	2	A.R.	2,68	2,47	3,09	3,69	4,12	3,21
KD	3	A.R.	4,23	3,84	3,16	6,50	2,92	4,13
BP	4	A.R.	4,53	3,93	3,94	7,30	5,08	4,96
RE	5	A.R.	3,72	4,71	4,70	6,46	4,10	4,74
BD	6	T.C.	3,87	4,68	4,72	4,09	4,18	4,31
MM	7	T.C.	3,59	3,69	3,57	6,80	4,46	4,42
VBA	8	T.C.	3,33	3,92	4,11	4,54	4,09	4,00
KL	9	T.C.	4,18	4,44	4,37	6,96	4,33	4,86
LA	10	T.C.	2,87	2,86	3,11	2,05	1,01	2,38
Requirements:		At least 46 out of the 50 individual exercise results for total inward leakage shall be not greater than 11 %. At least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than 8 %.						

50 out of the 50 individual exercise results for total inward leakage were not greater than 11 % and 10 out of the 10 individual wearer arithmetic means for the total inward leakage were not greater than 8%.

PASSED



7.17 Clogging

Clogging treatment with DRB 4/15 dolomite dust

Continuous flow through the dust chamber: 60 m³/h

	Conditioning	A.R.	T.C.	T.C	
	Sample	11	12	13	
	Requirement	Measured			
Temperature of the air, °C	23 ± 2 °C	21			
Relative humidity of the air, %	45 ± 15 %	54	45	45	
Concentration, mg/m ³	400±100 mg/m ³	300	498	452	
Exposure time, min	833 mgh/m ³	167	100	111	
Inhalation resistance, mbar at 95 l/min continuous flow	4 mbar	2,80	1,87	1,92	
Exhalation resistance at 95 l/min continuous flow	ahead	4 mbar	3,88	3,14	3,26
	vert. upwards		3,86	3,14	3,27
	vert. downwards		3,87	3,15	3,26
	left		3,87	3,16	3,26
	right		3,87	3,16	3,26
Paraffin aerosol concentration at 95 l/min flow	15-25 mg/m ³				
Paraffin penetration, %	max. 6 %	0,34	-	-	
Paraffin exposure, %	max. 6 %	-	1,38	-	
NaCl exposure, %	max. 6 %	-	-	1,43	

None of the measured values exceeded the maximum values.

PASSED



SMALL SIZE WITH EAR LOOP/HEAD BAND, WHITE COLOUR + DOLOMITE PERFORMANCE

(The head or ear band is relevant only at total inward leakage)





7.9.1 Total inward leakage

With sodium chloride aerosol. The masks were in good condition.

Number of subjects were replaced, because of not fitting/facial dimensions:0.....

with ear loop

Subjects facial dimensions				
Subject	Face length, mm	Face width, mm	Face depth, mm	Mouth width, mm
LA	123	140	105	60
VBA	110	115	115	55
NA	115	100	125	50
TLI	125	165	140	75
KD	160	120	110	53
GZ	154	149	113	65
OJ	130	105	107	54
TLA	115	130	110	53
RE	115	138	112	48
BD	120	130	135	55



Subject	Sample	Cond.	Total inward leakage, %					Mean, %
			Walk	Head left/right	Head up/down	Talk	Walk	
LA	14	A.R.	3,44	3,62	3,80	9,05	3,51	4,68
VBA	15	A.R.	2,93	3,23	3,05	3,20	2,93	3,07
NA	16	A.R.	4,37	4,16	4,16	6,08	5,41	4,84
TLI	17	A.R.	3,93	3,83	4,11	6,79	3,21	4,37
KD	18	A.R.	2,21	3,60	4,99	3,75	3,47	3,60
GZ	19	T.C.	3,72	3,76	2,87	6,35	3,28	4,00
OJ	20	T.C.	2,86	4,12	2,26	5,72	3,70	3,73
TLA	21	T.C.	3,32	3,40	3,69	5,22	3,30	3,79
RE	22	T.C.	2,33	2,06	3,14	9,58	2,24	3,87
BD	23	T.C.	1,50	0,95	1,81	1,52	1,60	1,48
Requirements:		<p>At least 46 out of the 50 individual exercise results for total inward leakage shall be not greater than 11 %.</p> <p>At least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than 8 %.</p>						

50 out of the 50 individual exercise results for total inward leakage were not greater than 11 % and 10 out of the 10 individual wearer arithmetic means for the total inward leakage were not greater than 8%.

PASSED



with head band

Subjects facial dimensions				
Subject	Face length, mm	Face width, mm	Face depth, mm	Mouth width, mm
NA	115	100	125	50
TLI	125	165	140	75
BP	120	125	116	57
KD	160	120	110	53
RE	115	138	112	48
BD	120	130	135	55
MM	113	138	123	63
VBA	110	115	115	55
KL	120	140	140	60
LA	123	140	105	60

Subject	Sample	Cond.	Total inward leakage, %					Mean, %
			Walk	Head left/right	Head up/down	Talk	Walk	
NA	24	A.R.	3,54	3,26	3,40	8,63	3,86	4,54
TLI	25	A.R.	3,10	4,19	3,59	3,48	3,89	3,65
BP	26	A.R.	4,64	4,70	4,00	5,68	4,12	4,63
KD	27	A.R.	3,34	4,99	3,46	6,22	3,09	4,22
RE	28	A.R.	3,37	4,18	3,47	5,75	2,07	3,77
BD	29	T.C.	3,98	3,88	4,27	4,77	4,46	4,27
MM	30	T.C.	3,52	3,03	3,00	5,45	3,64	3,73
VBA	31	T.C.	3,71	4,40	4,13	5,29	4,14	4,33
KL	32	T.C.	3,38	3,87	4,22	4,81	4,43	4,14
LA	33	T.C.	1,79	1,59	2,14	1,36	1,90	1,76
Requirements:		<p>At least 46 out of the 50 individual exercise results for total inward leakage shall be not greater than 11 %.</p> <p>At least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than 8 %.</p>						

50 out of the 50 individual exercise results for total inward leakage were not greater than 11 % and 10 out of the 10 individual wearer arithmetic means for the total inward leakage were not greater than 8%.

PASSED



7.9.2 Penetration of filter material: paraffin oil

Paraffin aerosol: concentration: 15-25 mg/m³ flow: 95 l/min

Sample	Conditioning	Penetration, %	Exposure, %
34	A.R.	0,12	NA
35	A.R.	0,15	NA
36	A.R.	0,13	NA
37	S.W.	0,45	NA
38	S.W.	0,52	NA
39	S.W.	0,40	NA
40	M.S→T.C.	NA	0,37
41	M.S→T.C.	NA	0,34
42	M.S→T.C.	NA	0,41
Maximum permitted:		6 %	

The penetration of the filter material did not exceed the maximum permitted 6 % in case of any masks.
PASSED

7.12 Carbon dioxide content of the inhalation air

Air supplied from breathing machine: 25 cycles/min and 2,0 l/stroke, carbon dioxide content of exhaled air 5 V/V%, air flow 0,5 m/s.

Ambient carbon dioxide level: 0,08 % (less than 0,1 %.)

Sample	Colour/Size	CO ₂ , V/V%
43	White S	0,42
44	White S	0,43
45	White S	0,41
Average		0,42

The carbon dioxide content of the inhalation air (dead space) did not exceed an average of 1,0 V/V %.
PASSED

7.16 Breathing resistance

Sample	Conditioning	Inhalation resistance, mbar		Exhalation resistance, mbar 160 l/min				
		30 l/min	95 l/min	ahead	vert.upwards	vert downwards	left	right
46	A.R.	0,28	1,17	2,26	2,27	2,28	2,29	2,29
47	A.R.	0,40	1,38	2,31	2,32	2,33	2,32	2,32
48	A.R.	0,38	1,23	2,19	2,20	2,21	2,22	2,19
Maximum permitted		0,7	2,4	3,0				

None of the measured values exceeded the maximum values.
PASSED



7.17 Clogging

Clogging treatment with DRB 4/15 dolomite dust

Continuous flow through the dust chamber: 60 m³/h

	Conditioning	A.R.	T.C.	T.C	
	Sample	49	50	51	
	Requirement	Measured			
Temperature of the air, °C	23 ± 2 °C	21			
Relative humidity of the air, %	45 ± 15 %	46	48	47	
Concentration, mg/m ³	400±100 mg/m ³	498	491	500	
Exposure time, min	833 mgh/m ³	100	102	100	
Inhalation resistance, mbar at 95 l/min continuous flow	4 mbar	2,37	2,33	2,41	
Exhalation resistance at 95 l/min continuous flow	ahead	4 mbar	3,51	3,97	3,67
	vert. upwards		3,52	3,95	3,67
	vert. downwards		3,51	3,96	3,66
	left		3,52	3,95	3,64
	right		3,51	3,94	3,65
Paraffin aerosol concentration at 95 l/min flow	15-25 mg/m ³				
Paraffin penetration, %	max. 6 %	0,41	-	-	
Paraffin exposure, %	max. 6 %	-	0,89	-	
NaCl exposure, %	max. 6 %	-	-	0,91	

None of the measured values exceeded the maximum values.

PASSED












Result of the routine test: PASSED

E N D O F T H E T E S T R E P O R T

LEGENDA SIMBOLI INSERITI NELLE SCATOLE DELLE MASCHERINE BIANCHE MODELLO:

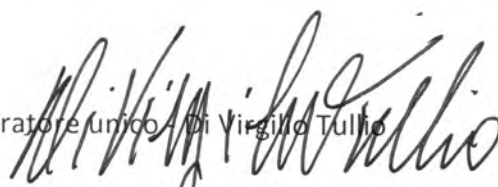
- Modello: 501 FFP2 NR D – Elastici auricolari
- Modello: 501 FFP2 NR D – Elastici auricolari taglia small
- Modello: 501 FFP2 NR D – Elastici nucali
- Modello: 501 FFP2 NR D – Elastici nucali taglia small

PITTOGRAMMI

	Lotto numero		Dispositivo monouso
	Data di fabbricazione		Proteggere il dispositivo dall'umidità e dagli agenti atmosferici
	Fabbricante		Proteggere dalla luce solare diretta
	Leggere il manuale prima di ogni utilizzo		Stoccare a temperatura compresa tra -5° e +38°C
	Dispositivo con scadenza		Umidità massima di stoccaggio < 80%
	Marcatura CE + numero di identificazione univoca dell'Organismo Notificato coinvolto nella procedura di valutazione della conformità		

Roma, 10/02/2023

L'Amministratore unico / Di Virgilio Tullio



Rotoform s.r.l.

Via dei Tamarindi, 14 - 00134 Roma
Tel. 06.71300197 - Fax 06.71302974
P.Iva 02111231003 -

Rotoform s.r.l.

Sede e Stabilimento:

00134 Roma (S. Palomba)

Via dei Tamarindi, 14

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Il marchio della
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