

DICHIARAZIONE UE DI CONFORMITÀ

Nome e indirizzo del fabbricante:

ROTOFORM Srl - via ardeatina km 20,400 (via dei tamarindi, 14) - 00134 Roma

Tel. 0671300197 - FAX 0671302974

P.IVA 02111231003 - C.F. 08653830581

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

Modello: 501 FFP2 NR

è conforme alle disposizioni:

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

Ente notificato:

GEP TESZT KFT. (No. 2233)

1037 Budapest, Jablonka u. 79 - Hungary

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

No. TD11/GT285/312/2104/E/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: **GEP TESZT KFT. (No.2233)**

Roma, li 29/04/2021



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 r.a.

Fax 06.71.30.29.74

Internet: www.rotoform.it

E-mail: info@rotoform.it



Il marchio della
gestione forestale
responsabile



GÉPTESZT Kft. Inspection Body

Notified Body under regulation
2016/425 (EU) personal protective equipment
Notified Body number in the EU on n°2233
Registration number: 3/2018

C E R T I F I C A T E

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

N° ED29/E199/2104/X1/E/2233

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

Name of manufacturer (controlled):

ROTOFORM s.r.l.

Address: Via Ardeatina, km. 20, 400 (Via dei Tamarindi, 14) 00134 Roma, ITALY

The above mentioned company is authorized to affix marking

CE 2233


on the personal protective equipment listed in Annex 1 of the certificate

Type of inspection: module C2

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.

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


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Hajdu Márton
Head of the Inspection Body

2021.12.28.
issue date

2022.12.31.
expiry date




Place of production: Via Ardeatina, km. 20, 400 (Via dei Tamarindi, 14) 00134
Roma, ITALY
Date of inspection: 2021.11.03.
Inspection report number: ED25/E199/2111/E/2233

Annex 1 of N° ED29/E199/2104/X1/E/2233

Description	Model/Type	EU type-examination certificate	Issued by
Particle filtering half-mask	501 FFP2 NR	TD11/GT285/312/2104/X2/E/2233	GÉPTESZT

Budapest, 2021.12.28.

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


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Hajdu Márton
Head of the Inspection Body


G É P T E S Z T



EU TYPE-EXAMINATION CERTIFICATE

Name of Certification Body: **GÉPTESZT Kft.** Phone: **+3612503531**
 EU notified body identification number: **2233** Fax: **+3614300888**
 Address: **Jablonka St. 79, 1037 Budapest, HUNGARY** E-mail: **gepteszt@gepteszt.hu**

Present EU type-examination certificate is valid only with the sealed identification sample (authentic sample) and the documents identified below. The EU type-examination certificate is not transferable.

1. Product designation: **Particle filtering half mask**
501 FFP2 NR FFP2 non reusable particle filtering half mask without valves.
 Serial / Model No.: 501 FFP2 NR
 Year of production: 2021
 2. Name and address of the holder of the certificate (Manufacturer or authorized representative):
Rotoform srl
 Address: Via Ardeatina, km. 20, 400 (Via dei Tamarindi, 14) 00134 Roma, ITALY
 3. Name and address of the Manufacturer: same as above (point 2)
 4. Protecting ability of PPE: Personal protective equipment providing respiratory system protection
 Category III. **EN 149:2001+A1:2009 class FFP2 NR**
 5. Identification data of the records of examination for compliance of PPE:
 - a. Certification Body: *GÉPTESZT Kft.*
 Record of examination: *VD35/285/2104/E/2233*
 - b. Identification of body: *NB2233*
 6. Documentation of the compliance with the essential health and safety protection requirements:
 Fully applied nationalized standard(s) during the production of the PPE:
 Category III. EN 149:2001+A1:2009 class FFP2 NR
- Annexes:
- Users information
 - Technical file
7.  Requirements for indicating the CE mark: The size of the CE marking may not be less than 5 mm. The CE mark must be located on the product label
 8. Further notes relating to the PPE: Manufacturer cannot place on the market or bring into service any Category III PPE without having established a formal agreement with a Notified Body about conformity to type assessment.

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

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.

The type tested complies with the regulation (EU) 2016/425 of the European Parliament of the Council.

The present certificate is valid until 29th April, 2026

Budapest, 29th April, 2021- HUNGARY

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

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 Budai István
 Head of Certification Body

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 EU TYPE-EXAMINATION 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 17025:2005 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)
00134 Roma, ITALY

Model: 501 FFP2 NR

Classification: FFP2 NR

Exhalation valve: NO

Inhalation valve: NO

Uses: non reusable

Project number: GT285

Test report number: VD35/285/2104/E/2233

Project worksheet number: VD-34-2021-285

Date of the test: 2021.04.16-04.29.

Samples received date: 2021.04.15.

Sample numbers: 285-1 - 285-46

Attachment: no

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

Issued: Budapest, 2021.04.29.

Budai Dániel
Director of Laboratory



Relevant standards, directives and requirements:

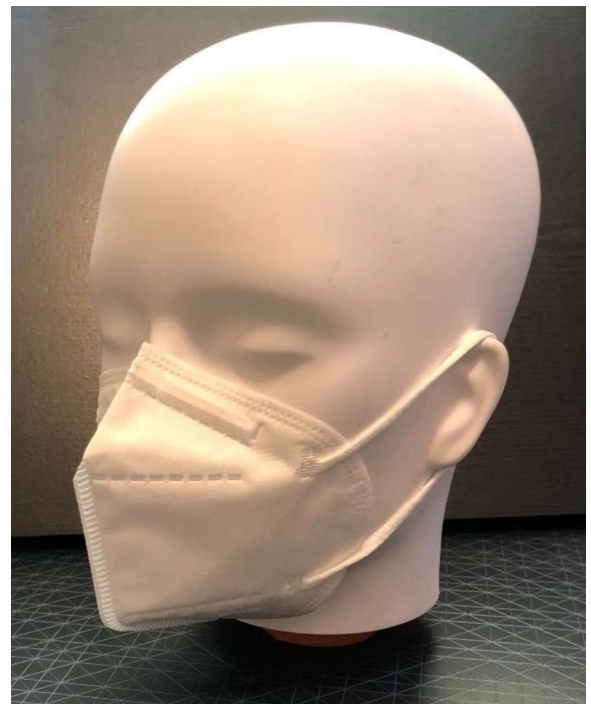
EN 149:2001+A1:2009 Filtering half masks to protect against particles

Description of the sample

The foldable mask is sold in white colour and consists of 5 layers:

1. Layer 1 (external) – 50 GSM no-woven cloth, waterproof, providing robustness to the mask such that it does not deform while breathing. White color.
2. Layer 2 – 25 GSM ultra-fine polypropylene filter cloth; combined with the filtering layer it ensures a barrier to particulates. White color
3. Layer 3 – 25 GSM ultra-fine polypropylene filter cloth; combined with the filtering layer it ensures a barrier to particulates. White color.
4. Layer 4 – 25 GSM no-woven cloth waterproof fabric, White color.
5. Layer 5 (internal) – 25 GSM no-woven cloth waterproof fabric, for a perfect and hypoallergenic seal on the face. It does not cause irritation or any other adverse effect to health. White color.

The elastic ear loop is made of spandex+polyester. The nose bat is made of PE, PP, galvanized wire.





Short description of EU-type tests:

Requirement	Test method	Description	Result
7.4	8.2	Packaging	Passed
7.5	8.2	Material	Passed
7.6	8.11	Cleaning and disinfecting	NA
7.7	8.4	Practical performance	Passed
7.8	8.2	Finish of parts	Passed
7.9.1	8.5	Total inward leakage	Passed
7.9.2	8.11	Penetration of filter material: NaCl	Passed
7.9.2	8.11	Penetration of filter material: paraffin oil	Passed
7.10	8.4 and 8.5	Compatibility with skin	Passed
7.11	8.6	Flammability	Passed
7.12	8.7	Carbon dioxide content of the inhalation air	Passed
7.13	8.4 and 8.5	Head harness	Passed
7.14	8.4	Field of vision	Passed
7.15	8.2, 8.3.4, 8.8	Exhalation valve(s)	NA
7.16	8.9	Breathing resistance	Passed
7.17	8.10	Clogging	NA
7.18	8.2	Demountable parts	NA
9	-	Marking	Passed
10	-	Information to be supplied by the manufacturer	Passed

Analysis and details of EU-type test results:

7.4 Packaging

Each mask is packed in a transparent polypropylene bag.

The packaging gives enough protection against mechanical damage or contamination.

PASSED

7.5 Material

- conditioning S.W.: Sample nr: 285-16 to 285-18

None of the particle filtering half masks have suffered mechanical failure of the facepiece or straps.

- conditioning T.C.: Sample nr.: 285-41 to 285-43

Particle filtering half masks did not collapse.

PASSED

7.6 Cleaning and disinfecting (only for reusable masks)

Because the mask is non-reusable, this test was not carried out.

NA

7.7 Practical performance

The particle filtering half masks are tested by practical performance tests under realistic conditions.

1. Walking test for 10 min
2. Work simulation tests:
 - walking on the level with headroom of $(1,3 \pm 0,2)$ m for 5 min;
 - crawling on the level with headroom of $(0,70 \pm 0,05)$ m for 5 min;
 - filling a small basket 20x in 10 min;

Subjects	Samples	Conditioning	Result
RE	285-1	A.R.	PASSED
SA	285-2	A.R.	PASSED

There were not any imperfections related to the wearer's acceptance.

PASSED



7.8 Finish of parts

Parts of the device are likely to come into contact with the wearer have no sharp edges or burrs.

PASSED

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
BB	75	90	70	30
BF	110	125	115	50
VB	100	110	80	75
NT	122	134	142	57
GL	90	85	80	50
NA	130	120	130	50
DF	108	136	105	55
BL	110	140	130	50
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	
BB	285-3	A.R.	3,78	2,86	2,64	1,68	1,70	2,53
BF	285-4	A.R.	3,09	3,70	2,31	7,08	2,89	3,81
VB	285-5	A.R.	3,52	3,08	2,41	3,12	3,56	3,14
NT	285-6	A.R.	3,72	3,75	2,70	1,97	2,63	2,95
GL	285-7	A.R.	2,16	1,79	2,19	1,73	1,55	1,88
NA	285-8	T.C.	1,41	3,05	3,83	3,34	1,33	2,59
DF	285-9	T.C.	1,77	0,97	1,93	1,33	1,44	1,49
BL	285-10	T.C.	3,73	3,34	3,20	1,54	3,25	3,01
RE	285-11	T.C.	2,32	2,36	2,31	1,94	2,13	2,21
BD	285-12	T.C.	3,05	2,82	2,31	4,30	2,97	3,09

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: NaCl

NaCl aerosol: concentration: 4-12 mg/m³, flow: 95 l/min

Sample	Conditioning	Penetration, %	Exposure, %
285-13	A.R.	0,44	NA
285-14	A.R.	0,41	NA
285-15	A.R.	0,43	NA
285-16	S.W.	0,30	NA
285-17	S.W.	0,35	NA
285-18	S.W.	0,37	NA
285-19	M.S→T.C.	NA	0,65
285-20	M.S→T.C.	NA	0,67
285-21	M.S→T.C.	NA	1,05
Maximum permitted:		6 %	

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

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, %
285-22	A.R.	0,45	NA
285-23	A.R.	0,83	NA
285-24	A.R.	0,98	NA
285-25	S.W.	0,41	NA
285-26	S.W.	0,36	NA
285-27	S.W.	0,37	NA
285-28	M.S→T.C.	NA	2,09
285-29	M.S→T.C.	NA	0,99
285-30	M.S→T.C.	NA	1,48
Maximum permitted:		6 %	

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

PASSED

7.10 Compatibility with skin

Materials that may come into contact with the wearer's skin are not known to be likely to cause irritation or any other adverse effect to health.

During the Practical performance test there were no problems.

During the Total inward leakage test there were no problems.

PASSED

7.11 Flammability

Sample	Conditioning
285-33	T.C.
285-34	T.C.
285-31	A.R.
285-32	A.R.

The materials used do not present a danger for the wearer and are not of highly flammable nature. The samples did not burn.

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	CO ₂ , V/V%
285-35	0,46
285-36	0,50
285-37	0,52
Average	0,49

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

PASSED

7.13 Head harness

There were no adverse comments regarding security following limited practical performance and total inward leakage testing.

The product satisfied the total inward leakage requirements. See part 7.9.1. for results.

PASSED



7.14 Field of vision

Sample
285-1
285-2

During the practical performance test the field of vision was not affected adversely by wearing mask.
PASSED

7.15 Exhalation valve(s)

NA

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
285-38	A.R.	0,40	1,32	2,13	2,12	2,12	2,14	2,16
285-39	A.R.	0,41	1,35	2,17	2,18	2,16	2,17	2,16
285-40	A.R.	0,40	1,34	2,16	2,15	2,15	2,17	2,18
285-41	T.C.	0,37	1,22	1,92	1,93	1,93	1,92	1,92
285-42	T.C.	0,39	1,25	2,03	2,04	2,05	2,04	2,03
285-43	T.C.	0,38	1,21	1,97	1,99	1,98	1,97	1,98
285-44	S.W.	0,40	1,38	2,18	2,19	2,18	2,17	2,18
285-45	S.W.	0,40	1,31	2,17	2,18	2,17	2,17	2,16
285-46	S.W.	0,41	1,36	2,19	2,19	2,20	2,19	2,20
Maximum permitted		0,7	2,4	3,0				

None of the measured values exceeded the maximum values.

PASSED

7.17 Clogging

The optional dolomit clogging test was not required by manufacturer.

NA

7.18 Demountable parts

The device does not contain demountable parts.

NA

9. Marking

The marking information is complete and clearly and durably marked on the packaging.

The marking information is complete and clearly and durably marked on the particle filtering half mask.

PASSED

10. Information to be supplied by the manufacturer

Information to be supplied by the manufacturer accompany every smallest commercial available package and contain all information necessary for trained and qualified persons.











PASSED

Result of EU-type test:

The above described **501 FFP2 NR particle filtering half mask** at the time of the test **conformed** to the test requirements of EN 149:2001+A1:2009 class FFP2 NR at the close date of test report.

PICTOGRAM LEGEND INSERTED ON THE PACKAGING OF THE WHITE AND COLORED MASKS: **MOD. 501 FFP2 NR**

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%.
CE 2233	Marcatura CE + numero di identificazione univoca dell'Organismo Notificato coinvolto nella procedura di valutazione della conformità		