

DICHIARAZIONE UE DI CONFORMITA'

Nome e indirizzo del fabbricante:

ROTOFORM Srl – 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 nucali taglia regular**
- **Modello: 501 FFP2 NR D – Elastici nucali 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, 02/03/2026

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

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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

EU TYPE-EXAMINATION CERTIFICATE

Conformity assessment procedure - module B

TD11-1141-2605-GT0285-C02

Category:	III.
Designation:	Particle filtering half mask
Brand:	-
Model:	501 FFP2 NR D
Requirement:	EN 149:2001 + A1:2009
Classification:	FFP2 NR D
Description:	FFP2 NR D (non reusable with dolomite performance) valveless flat-folded-type particle filtering half mask with nose bar, ear loop or head band, welded marking in white colour. Consists of 5 layers. In regular and small size.
License holder:	ROTOFORM SRL Via Ardeatina, Km. 20, 400 (Via Dei Tamarindi, 14) 00134 Roma, Italy
Reference:	TD09.1-0305-2605-GT0285-C02

The PPE type complies with the applicable essential health and safety requirements of Regulation (EU) 2016/425.
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: 12/05/2026
Date of expiry: 11/05/2031

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

A handwritten signature in blue ink, appearing to read 'Andrea Nagy', is written over a horizontal line.

Andrea Nagy
Certification Manager

Marking and instructions have been assessed in 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 and in point 7.7 of Annex V of Regulation (EU) 2016/425.
The Manufacturer shall inform GÉPTESZT Kft. 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. (point 7.2 of Annex V of Regulation (EU) 2016/425)
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.
Legal remedy can be applied against the condition stated in the EU type-examination certificate. The application for appeal should be submitted to the CEO of GÉPTESZT Kft. and the application will be judged by the board of GÉPTESZT Kft. Certification Body.

EU TYPE-EXAMINATION CERTIFICATE

Annex:



GÉPTESZT

CERTIFICATE FOR INTERNAL PRODUCTION CONTROL

Conformity to type based on internal production control plus supervised product checks at random intervals - module C2

ED29-0874-2603_A0114

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

Reference: SUR-C2-0079-2603_A0114

Place of production: *Via Ardeatina, Km. 20, 400 (Via Dei Tamarindi, 14) 00134 Roma, Italy*

Date of inspection: 24. 03. 2026

The examined personal protective equipment (PPE) is in conformity with the types described in the EU type-examination certificates and satisfies the applicable requirements of Regulation (EU) 2016/425.

The inspected company is authorized to affix the CE mark and the corresponding Notified Body number

CE 2233

*- in compliance with the applicable rules and conditions -
to the PPE listed in the Annex of this certificate.*

Date of issue: 24. 03. 2026
Date of expiry: 31. 12. 2026

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


Lajos Tóth

Inspection Manager

The Certificate for internal production control remains the property of GÉPTESZT Kft. and will be withdrawn in case of existence of conditions stated in Article 32 and in point 7.7 of Annex V of Regulation (EU) 2016/425.

The Manufacturer shall inform GÉPTESZT Kft. 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. (point 7.2 of Annex V of Regulation (EU) 2016/425)

Legal remedy can be applied against the condition stated in the Certificate for internal production control.

The application for appeal should be submitted to the CEO of GÉPTESZT Kft. and the application will be judged by the board of GÉPTESZT Kft. Inspection Body.

CERTIFICATE FOR INTERNAL PRODUCTION CONTROL

Annex

ID	Model	Requirement	Certificate
GT0285-P08	501 FFP2 NR D	EN 149:2001 + A1:2009	TD11-0963-2506-GT0285-X04

G É P T E S Z T

SURVEILLANCE REPORT

Annual surveillance report - module C2

N°:	SUR-C2-0079-2603_A0114	
Period covered by the report:	01/01/2026 - 31/12/2026	
Manufacturer / Own Brand Manufacturer		
Company name:	ROTOFORM SRL	
Office address:	Via Ardeatina, Km. 20, 400 (Via Dei Tamarindi, 14) 00134 Roma, Italy	
Place of production:	Via Ardeatina, Km. 20, 400 (Via Dei Tamarindi, 14) 00134 Roma, Italy	
Representative person:	Mario Di Virgilio	CEO
Email:	m.divirgilio@rotoform.it	
Phone:	+39 06 713 00 197	

General references

Regulation (EU) 2016/425:	Annex VII
Recommendation for use sheet:	PPE-R/00.007
Harmonised standards / technical specifications within the scope of the surveillance:	See in annual visit report

Referenced documents

Visit report:	ED24-0062-2603_A0114
Other reference(s):	Test report: VD35-0162-2512-GT0285-P07 s

Details of audit

Location visited:	Same as place of production above.
Start date:	19. 03. 2026
End date:	19. 03. 2026

Annual assessment of product compliance with standard / specification and type-examined

(reference 2A of RFU 00.007)

Details of assessment

Selection carried out by:	Lajos TÓTH
Relationship to GÉPTESZT:	Inspection manager at GÉPTESZT
Company representative:	Same as the representative person above.
Title:	Same as the representative person above.

Relationship of company visited to type-examination certificate holder

<input checked="" type="checkbox"/> Certificate Holder	<input type="checkbox"/> Production site	<input type="checkbox"/> Importer
<input type="checkbox"/> Secondary production site	<input type="checkbox"/> Distributor	<input type="checkbox"/> Retail Outlet
<input type="checkbox"/> European office of same company		
<input type="checkbox"/> Other:		

SURVEILLANCE REPORT

Annual assessment of product compliance with standard / specification and type-examined

(reference 2A of RFU 00.007)

Conclusion

Result of sample selection:	positive
Result of product testing:	positive
Sample selection and testing demonstrated compliance with the reference specification / standard and type-examined:	yes

Annual assessment of production not being homogeneous

(reference 2B of RFU 00.007)

Method employed to perform assessment

- (i) - On-site review of production and test records.
- (ii) - On-site audit of production control.
- (iii) - Production non-homogeneity assessed by selection of a single, large sample.
- (iv) - Production non-homogeneity assessed by assessment of samples throughout the year.

Details of assessment

Assessment(s) carried out by:	Lajos TÓTH
Relationship to GÉPTESZT:	Inspection manager at GÉPTESZT
Company representative:	Same as the representative person above.
Title:	Same as the representative person above.

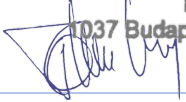
Conclusion

According to our judgement, the assessment concluded that production was homogeneous: yes

Justification of non-conformities

Conclusion of GÉPTESZT:	
Overall conclusion of the annual surveillance:	positive

Signature

	Sign and stamp: GÉPTESZT KFT. EVE Ellenőrző Szervezet NB 2233 1037 Budapest, Jablonka u. 79.
Date of issue:	24. 03. 2026
	 Lajos Tóth Inspection Manager

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 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)
00134 Roma, Italy

Model: 501 FFP2 NR D

Classification: FFP2 NR D

Exhalation valve: NO

Inhalation valve: NO

Uses: non reusable (NR)

Project number: GT0285-P07

Test report number: VD35-0162-2512-GT0285-P07

Project worksheet number: VD34-0203-2512-GT0285-P07

Date of the test: 12/12/2025

Samples received date: 04/12/2025

Sample numbers: 1 - 3

Attachment: no

Issued: Budapest, 15/12/2025

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

.....

Dániel Budai
Director of Laboratory



Relevant standards, directives and requirements:

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

Description of the sample

Thee foldable mask is sold in white colour and consists of 5 layers and produced with headband or ear loop.

1. Layer 1 (external) – 50 GSM no-woven cloth, waterproof, providing robustness to the mask such that it does not deforms 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 or headband is made of spandex. The nose bar is made of PE, PP, galvanized wire.



Short description of the tests:

Requirement	Test method	Description	Result
7.9.2	8.11	Penetration of filter material: paraffin oil	PASSED

**Analysis and details of the test results:****7.9.2 Penetration of filter material: paraffin oil**Paraffin aerosol: concentration: 15-25 mg/m³, flow: 95 l/min

Sample	Conditioning	Penetration, %	Exposure, %
1	A.R.	0,45	NA
2	A.R.	0,37	NA
3	A.R.	0,36	NA
Maximum permitted:		6 %	

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

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

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

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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

Dichiarazione di conformità UE

PRODOTTO	MASCHERINA FFP2 NR D DI TIPO IIR MONOUSO IN TNT AD ALTA TRASPIRABILITÀ CON ELASTICI
IDENTIFICATIVO ATTRIBUITO DAL FABBRICANTE (MODELLO)	Mod. 501 FFP2 NR D - elastico auricolate Tg regular Mod. 501 FFP2 NR D - elastico auricolate Tg small Mod. 501 FFP2 NR D - elastico nucale Tg regular Mod. 501 FFP2 NR D - elastico nucale Tg small
CONFORMITÀ CE	 2375589 Regolamento europeo 2017/745 Dispositivo medico classe I
PRINCIPALI NORME TECNICHE APPLICATE	UNI EN 14683:2019 UNI EN ISO 10993-1:2010 UNI EN ISO 10993-5:2009
FABBRICANTE	Rotoform Srl Via dei Tamarindi, 14 - 00134 Roma P. Iva 02111231003 - C.F. 08653830581


Rotoform s.r.l.
 Via dei Tamarindi, 14 - 00134 Roma
 Tel. 06.71.30.01.97 - Fax 06.71.30.29.74
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 www.rotoform.it - info@rotoform.it
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INDUSTRIA POLIGRAFICA

La seguente dichiarazione è rilasciata dal sig. **Tullio Di Virgilio**, Amministratore Unico dell'Azienda **Rotoform Srl** con sede in 00134 Roma - via dei Tamarindi, 14 sotto la propria esclusiva responsabilità.

Mod. 501 FFP2 NR D - elastico auricolate Tg regular / Mod. 501 FFP2 NR D - elastico auricolate Tg small / Mod. 501 FFP2 NR D - elastico nucale Tg regular / Mod. 501 FFP2 NR D - elastico nucale Tg small tutte TYPE IIR "MASCHERINA FFP2 di TIPO IIR MONOUSO IN TNT AD ALTA TRASPIRABILITÀ CON ELASTICI" è un dispositivo medico di Classe I, conforme al Regolamento (UE) 2017/745 relativo ai dispositivi medici e rispetta tutti i requisiti applicabili specificati nell'allegato I di detto regolamento. Il prodotto, inoltre,

- risponde ai requisiti della norma UNI EN 14683:2019 "Mascherine facciali ad uso medico – requisiti e metodi di prova" risultando un Dispositivo Medico di Tipo IIR, secondo la seguente tabella:

Test	u.m.	Risultato	Tipo I	Tipo II	Tipo IIR
Bacterial filtration efficiency (BFE)	%	99,7	≥95	≥98	≥98
Differential pressure	Pa/cm2	57,4	<40	<40	<60
Microbial Cleanliness	cfu/g	10,0	≤30	≤30	≤30

- risponde ai requisiti di biocompatibilità secondo la norma UNI EN ISO 10993-1:2010 "Valutazione biologica dei dispositivi medici – Rapporto di prova n° 220718020/1 e n° 220830007/1.
- è progettato e prodotto nell'ambito di un sistema di gestione della qualità certificato conforme a ISO 9001:2015 dall'organismo di certificazione ACM UKAS certificato n° 08588Q emesso il 08/05/2009

Roma, 02/03/2026

Nome: Posizione: Tullio Di Virgilio

Per conto di: Amministratore Unico

Firma:

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Il marchio della gestione forestale responsabile



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Elenco dei dispositivi medici

Criteri di ricerca:

- Denominazione fabbricante:
- Codice fiscale fabbricante:
- Partita IVA / VAT number fabbricante:
- Codice nazione fabbricante:
- Denominazione mandatario:
- Codice fiscale mandatario:
- Partita IVA / VAT number mandatario:
- Codice nazione mandatario:
- Tipologia dispositivo:
- Identificativo di registrazione attribuito dal sistema BD/RDM: **2375589**
- Codice attribuito dal fabbricante:
- Nome commerciale e modello:
- Classificazione CND:
- Descrizione CND:
- Normativa:
- Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al: 25/02/2023

DISPOSITIVO MEDICO/ASSEMBLATO							FABBRICANTE/ASSEMBLATORE							
TIPOLOGIA	DI	ISCRITTO AL	CODICE ATTRIBUITO DAL	NOME	CND	NORMATIVA	CLASSE	DATA PRIMA	DATA FINE	RUIOLO	DENOMINAZIONE	CODICE	PARTITA	NAZIONE
DISPOSITIVO	REGISTRAZIONE	REPERTORIO	FABBRICANTE/ASSEMBLATORE	COMMERCIALE			CE	PUBBLICAZIONE	IMMISSIONE	IN	COMMERIO	FISCALE	IVA/VAT	
	BD/RDM			E MODELLO					IN	AZIENDA			NUMBER	
Dispositivo	2375589	N	501 FFP2 NR D	TYPE IIR 501 FFP2 NR D		T020604 - MASCHERE FACCIALI AD USO MEDICO TIPO II e IIR	D.L.vo 46/97 attuazione Dir. CE 93/42	24/02/2023	I - Classe I non sterile e senza funzioni di misura	FABBRICANTE	ROTOFORM S.R.L.	08653830581	02111231003	IT










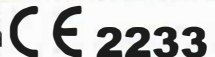
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LEGENDA SIMBOLI INSERITI NELLE SCATOLE DELLE MASCHERINE BIANCHE MODELLO:

- 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°C 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, 02/03/2026

L'Amministratore unico - Di Virgilio Tullio



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