Rotoform®
INDUSTRIA POLIGRAFICA

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. TD11-1141-2605-GT0285-C02

Il DPI e 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 -

CE

GÉPTESZT Kft.
Notified body in the EU: N°2233
Jablonka St. 79., Budapest, 1037, HUNGARY
gepteszt@gepteszt.hu
+36 1 250 3531

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 Tanusító Szervezet
NB 2233
1037 Budapest, Jablonka u.79.

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

GÉPTESZT Kft.
Notified body in the EU: N°2233
Jablonka St. 79., Budapest, 1037, HUNGARY
gepteszt@gepteszt.hu
+36 1 250 3531

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

GÉPTESZT

GÉPTESZT Kft.
Notified body in the EU: N°2233
Jablonka St. 79., Budapest, 1037, HUNGARY
gepteszt@gepteszt.hu
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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					
☑	Certificate Holder	☐	Production site	☐	Importer
☐	Secondary production site	☐	Distributor	☐	Retail Outlet
☐	European office of same company				
☐	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

COMPONENT OR SUB-COMPONENT	MATERIAL	GRADE
Nose Bar	Double wire PP material	90 ± 2 mm
Ear Loop	28% Spandex 72% Polyester yarn	2+190 mm (± 15 mm); width = 5 mm.
Waterproof fabric (external Layer)	Non-woven cloth fabric White and colors	50 ± 2,5 g/m^2
FILTER_ 2nd Layer	Non-woven cloth fabric	25 ± 2,5 g/m^2
Melt blown cloth filter layer 2 x filtering layers	Ultra fine polypropylene filter cloth	25 ± 2,5 g/m^2
FILTER_ 4nd Layer	Non-woven cloth fabric	25 ± 2,5 g/m^2
Skin care fabric (internal Layer)	Non-woven cloth fabric	25 ± 2,5 g/m^2



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/m^3, 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

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 m^3/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/m³		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:		**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

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:		**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

7.9.2 Penetration of filter material: paraffin oil

Paraffin aerosol: concentration: 15-25 mg/m^{3,} 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 reistance, 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 m^3/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/m³		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

<u>Result of the routine test</u>: PASSED

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

Rotoform®
INDUSTRIA POLIGRAFICA

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	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

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P.Iva 02111231003 -

Rotoform®
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

Rotoform Srl

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Il marchio della gestione forestale responsabile

Stampa | Scarica il dataset

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 DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	NORMATIVA	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
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	I - Classe I non sterile e senza funzioni di misura	24/02/2023		FABBRICANTE	ROTOFORM S.R.L.	08653830581	02111231003	IT

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Indietro

Rotoform®
INDUSTRIA POLIGRAFICA

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

LOT	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	+38°C -5°C	Stoccare a temperatura compresa tra -5° e +38°C
	Dispositivo con scadenza	<90%	Umidità massima di stoccaggio < 80%.
CE 2233	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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