

## 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](mailto: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, 02/01/2024

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)

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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

## 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.

G É P T E S Z T



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 ANNUAL SURVEILLANCE REPORT

Document No: ED25/143/2312/P114  
C2 certificate No: ED29/143/2312/P114 from 05 December, 2023  
Model: 501 FFP2 NR D  
Certificate holder: ROTOFORM SRL  
Via Dei Tamarindi, 14 00134 Roma, Italy  
Period covered by report: 01 January 2024 - 31 December 2024

### General reference documents:

Recommendation for use sheet, 00.007 and PPE Regulation 2016/425/EU, Module C2  
EU Type-examination certificate number covered by the surveillance: TD11/GT285/312/2104/E/2233 from 29 April, 2021  
Harmonized standard(s) / technical spec. within the scope of the surveillance: EN 149:2001+A1:2009

### A. Annual assessment of product in compliance with the referenced specification and standard(s) - reference 2A of RfU 00.007

1. Manufacturer: ROTOFORM SRL  
Location visited: Via Dei Tamarindi, 14 00134 Roma, Italy  
Date of visit: on 15 November, 2023  
2a. Assessment carried by: Lajos Tóth - Inspection manager at GÉPTESZT Kft.  
2b. Company representative: Francesco Lupo - Sales manager  
2c. Relationship of visited company to type-examination certificate holder: Factory  
List of PPEs available: 501 FFP2 NR D 20 pcs  
Attached reference document: test report: VD36/GT285-E3/2023/EN from 24 November, 2023  
3. Result of sample selection: positive Result of product testing: positive  
4. The selection of the samples and the demonstrated testing are in compliance with the referenced specification and standard(s).

### B. Annual assessment of production not being homogeneous - reference 2B of RfU 00.007

1. Method employed to perform assessment: 2B(ii) On-site audit of production control  
2a. Assessment carried by: Balázs Völcssei - Program manager at GÉPTESZT Kft.  
2b. Company representative: Francesco Lupo - Sales manager  
Attached reference document(s): visit report: ED24/1062/2311/EN/2233 from 15 November, 2023

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

Overall conclusion of the annual surveillance: positive

Name and position: Lajos Tóth - Inspection manager

Date of issue: 05 December, 2023

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



Lajos Tóth  
Inspection manager

## MODULE C2 CERTIFICATE

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

**ED29/143/2312/P114**

Manufacturer: **ROTOFORM SRL**  
Address: Via Dei Tamarindi, 14 00134 Roma, Italy  
Place of inspection: Via Dei Tamarindi, 14 00134 Roma, Italy  
Date of inspection: 15 November, 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: 05.12.2023  
Date of expiry: 31.12.2024

  
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: ED29/143/2312/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 D	Particle filtering half mask	TD11/GT285/312/2104/E/2233	Gépteszt

A large, light gray watermark of the GÉPTESZT logo is centered on the page. It features three overlapping triangles (blue, green, white) above the company name 'GÉPTESZT' in a bold, uppercase, sans-serif font.

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

Address: Jablonka St. 79., Budapest, 1037, HUNGARY  
e-mail: [nb2233@gepteszt.hu](mailto:nb2233@gepteszt.hu)  
web: [www.gepteszt.hu](http://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

<b>COMPONENT OR SUB-COMPONENT</b>	<b>MATERIAL</b>
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 <sup>nd</sup> Layer	Non-woven cloth fabric
Melt blown cloth filter layer 2 x filtering layers	Ultra fine polypropylene filter cloth
FILTER_ 4 <sup>nd</sup> 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
<b>Requirements:</b>		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<sup>3</sup>/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 <sup>3</sup>		400±100 mg/m <sup>3</sup>	300	498	452
Exposure time, min		833 mgh/m <sup>3</sup>	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 <sup>3</sup>			
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
<b>Requirements:</b>		<p><b>At least 46 out of the 50 individual exercise results for total inward leakage shall be not greater than 11 %.</b></p> <p><b>At least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than 8 %.</b></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
<b>Requirements:</b>		<p><b>At least 46 out of the 50 individual exercise results for total inward leakage shall be not greater than 11 %.</b></p> <p><b>At least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than 8 %.</b></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/m<sup>3</sup> 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
<b>Maximum permitted:</b>		<b>6 %</b>	

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 <sub>2</sub> , V/V%
43	White S	0,42
44	White S	0,43
45	White S	0,41
<b>Average</b>		<b>0,42</b>

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
<b>Maximum permitted</b>		<b>0,7</b>	<b>2,4</b>	<b>3,0</b>				

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<sup>3</sup>/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 <sup>3</sup>	400±100 mg/m <sup>3</sup>	498	491	500	
Exposure time, min	833 mgh/m <sup>3</sup>	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 <sup>3</sup>				
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

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

  
**Rotoform s.r.l.**  
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**Rotoform s.r.l.**

Sede e Stabilimento:  
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Il marchio della  
gestione forestale  
responsabile

# 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)	%	<b>99,7</b>	≥95	≥98	≥98
Differential pressure	Pa/cm2	<b>57,4</b>	<40	<40	<60
Microbial Cleanliness	cfu/g	<b>10,0</b>	≤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, 24/02/2023

Nome: Posizione: Tullio Di Virgilio

Per conto di: Amministratore Unico

Firma:

Rotoform Srl  
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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



[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							
IDENTIFICATIVO				NOME			DATA FINE			PARTITA IVA/VAT				
TIPOLOGIA	DI	ISCRITTO AL	CODICE ATTRIBUITO DAL	COMMERCIALE	CND	NORMATIVA	CLASSE	DATA PRIMA	IMMISSIONE	RUIOLO	DENOMINAZIONE	CODICE	IVA/VAT	NAZIONE
DISPOSITIVO	REGISTRAZIONE	REPERTORIO	FABBRICANTE/ASSEMBLATORE	E MODELLO			CE	PUBBLICAZIONE	IN	AZIENDA	COMMERCIO	FISCALE	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	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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LEGENDA SIMBOLI INSERITI NELLE SCATOLE DELLE MASCHERINE BIANCHE MODELLO:

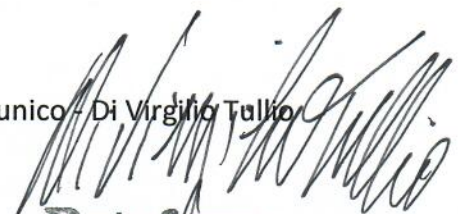
- Modello: 501 FFP2 NR D – Elastici auricolari
- Modello: 501 FFP2 NR D – Elastici auricolari taglia small
- Modello: 501 FFP2 NR D – Elastici nucali
- Modello: 501 FFP2 NR D – Elastici nucali taglia small

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, 02/01/2024

L'Amministratore unico - Di Virgilio Tullio



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