Rotoform®
INDUSTRIA POLIGRAFICA

DICHIARAZIONE UE DI CONFORMITÀ

Nome e indirizzo del fabbricante:

ROTOFORM SRL - Via dei Tamarindi, 14 (già via Ardeatina, km 20,400) - 00134 Roma
Tel. 06-71300197 - Fax 06-71302974 - P.Iva 02111231003 - C.F. 08653830581
Dichiara sotto la propria responsabilità che il Dispositivo di Protezione Individuale di seguito descritto:

Modello: 501 FFP2 NR - nei seguenti colori:

BIANCO - NERO - VERDE SCURO - BORDO' - GLICINE - GIALLO - VERDE - ROSA ARANCIONE - CICLAMINO - BLU - GRIGIO - VERDE MELA - LAVANDA - ROSSO

sono conformi alle disposizioni:

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

Ente notificato **GEPTESZT KFT. (No. 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/GT285/312/2104/E/2233 - No. TD11GT285-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, lì 10/02/2023

CE

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 -

GÉPTESZT Nº.: TD11/GT285/312/2104/E/2233

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

.....
Budai István
Head of Certification Body

GÉPTESZT Kft.
Notified Body No. 2233
Address: Jablonka St. 79., Budapest, 1037, HUNGARY
Phone: +3612503531
E-mail: gepteszt@gepteszt.hu

MODULE C2 CERTIFICATE

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

ED29/111/2302/P114

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

The above mentioned company is authorized to affix marking

CE 2233

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

Type of inspection: module C2
The results of control are covered by the EU type-examination certificate(s) listed in Annex 1 of the certificate.

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

Lajos Tóth
Inspection manager

Date of issue:	09.02.2023
Date of expiry:	31.12.2023

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

GÉPTESZT Kft.
Notified Body No. 2233
Address: Jablonka St. 79., Budapest, 1037, HUNGARY
Phone: +3612503531
E-mail: gepteszt@gepteszt.hu

MODULE C2 CERTIFICATE

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

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

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

GÉPTESZT Kft.
Notified Body No. 2233
Address: Jablonka St. 79., Budapest, 1037, HUNGARY
Phone: +3612503531
E-mail: gepteszt@gepteszt.hu

MODULE C2 ANNUAL SURVEILLANCE REPORT

Document No:	**ED25/111/2302/P114**	
C2 certificate No:	**ED29/111/2302/P114**	from 09 February, 2023
Model:	**501 FFP2 NR**	
Certificate holder:	**ROTOFORM SRL**	
	Via Ardeatina, Km. 20, 400 (Via Dei Tamarindi, 14) 00134 Roma, Italy	
Period covered by report:	01 January 2023 - 31 December 2023	

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 Ardeatina, Km. 20, 400 (Via Dei Tamarindi, 14) 00134 Roma, Italy	
Date of visit:	on 25 January, 2023	
2a. Assessment carried by:	Balázs Völcsei - Program manager at GÉPTESZT Kft.	
2b. Company representative:	Mario Di Virgilio	
2c. Relationship of visited company to type-examination certificate holder:	Factory	
List of PPEs available:	501 FFP2 NR	100 pcs
Attached reference document:	test report: VD36/GT285-E2/2023/EN	from 09 February, 2022

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 Völcsei - Program manager at GÉPTESZT Kft.	
2b. Company representative:	Mario Di Virgilio	
Attached reference document(s):	visit report: ED24/1044/2301/EN/2233	from 25 January, 2023

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

Overall conclusion of the annual surveillance: positive

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

Name and position: Lajos Tóth - Inspection manager

Date of issue: 09 February, 2023

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
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) 00134 Roma, ITALY
Model:	**501 FFP2 NR**
Classification:	**FFP2 NR**
Exhalation valve	**no**
Inhalation valve:	**no**
Uses:	**non reusable (NR)**
Project number:	**GT285**
Test report number:	**VD36/GT285-E2/2023/EN**
Project worksheet number:	**VD34/2023/GT285-E2**
Date of the test:	**7th and 9th January, 2023.**
Samples received date:	**30th January, 2023.**
Sample numbers:	**1-45**
Attachment:	**no**
Issued:	**Budapest, 9th February, 2023.**

GÉPTESZT KFT.
EVE Vizsgáló Laboratórium
NB 2233
1037 Budapest, Jablonka u. 79.
Labor: 1032 Budapest, Gyenes u.13.

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 multiple colours 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 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 is made of spandex+polyester. The nose bat is made of PE, PP, galvanized wire.

Short description of routine tests:
The routine tests were carried out within the annual C2 audit, date: 25th January, 2023.

Requirement	Test method	Description	Result
7.16	8.9	Breathing resistance	Passed

Analysis and details of routine test results:

7.16 Breathing resistance

Sample	Colour	Conditioning	Inhalation resistance, mbar		Exhalation reistance, mbar 160 l/min				
			30 l/min	95 l/min	ahead	vert.upwards	vert downwards	left	right
1	dark green	A.R.	0,31	1,12	1,85	1,86	1,85	1,84	1,86
2	dark green	A.R.	0,36	1,14	1,84	1,83	1,82	1,81	1,83
3	dark green	A.R.	0,33	1,13	1,87	1,86	1,86	1,83	1,84
4	bordeaux	A.R.	0,29	1,09	1,79	1,78	1,77	1,79	1,78
5	bordeaux	A.R.	0,34	1,15	1,89	1,89	1,88	1,87	1,88
6	bordeaux	A.R.	0,37	1,18	1,85	1,86	1,84	1,85	1,86
Maximum permitted			**0,7**	**2,4**	**3,0**				

None of the measured values exceeded the maximum values.
PASSED

7.16 Breathing resistance

Sample	Colour	Conditioning	Inhalation resistance, mbar		Exhalation reistance, mbar 160 l/min				
			30 l/min	95 l/min	ahead	vert.upwards	vert downwards	left	right
7	white	A.R.	0,32	1,04	1,86	1,87	1,88	1,86	1,87
8	white	A.R.	0,32	1,03	1,88	1,89	1,87	1,88	1,89
9	white	A.R.	0,31	1,04	1,87	1,86	1,88	1,87	1,88
10	whisteria	A.R.	0,33	1,07	1,85	1,84	1,85	1,84	1,83
11	whisteria	A.R.	0,31	1,03	1,81	1,80	1,81	1,79	1,82
12	whisteria	A.R.	0,29	1,01	1,79	1,78	1,77	1,78	1,79
13	yellow	A.R.	0,36	1,17	1,94	1,93	1,92	1,91	1,91
14	yellow	A.R.	0,34	1,15	1,90	1,91	1,93	1,92	1,92
15	yellow	A.R.	0,35	1,16	1,92	1,90	1,89	1,90	1,91
16	green	A.R.	0,30	1,12	1,82	1,83	1,84	1,83	1,82
17	green	A.R.	0,32	1,12	1,83	1,84	1,85	1,83	1,84
18	green	A.R.	0,29	1,14	1,79	1,80	1,79	1,78	1,79
19	pink	A.R.	0,34	1,23	1,93	1,94	1,93	1,94	1,92
20	pink	A.R.	0,30	1,13	1,90	1,91	1,90	1,91	1,89
21	pink	A.R.	0,33	1,17	1,91	1,92	1,91	1,93	1,92
22	orange	A.R.	0,29	1,02	1,88	1,89	1,88	1,87	1,88
23	orange	A.R.	0,33	1,13	1,84	1,83	1,84	1,85	1,84
24	orange	A.R.	0,30	1,08	1,86	1,84	1,84	1,86	1,85
25	cyclamen	A.R.	0,31	1,07	2,02	2,01	2,02	2,01	2,02
26	cyclamen	A.R.	0,33	1,16	1,91	1,91	1,93	1,93	1,92
27	cyclamen	A.R.	0,34	1,18	1,93	1,94	1,95	1,93	1,95
28	blue	A.R.	0,30	1,06	1,94	1,93	1,94	1,93	1,91
29	blue	A.R.	0,32	1,12	1,97	1,96	1,96	1,95	1,96
30	blue	A.R.	0,29	1,01	1,89	1,88	1,89	1,88	1,87
31	gray	A.R.	0,34	1,20	1,93	1,94	1,94	1,95	1,94
32	gray	A.R.	0,31	1,13	1,87	1,88	1,89	1,88	1,89
33	gray	A.R.	0,36	1,26	2,01	2,00	2,01	2,02	2,03
34	green apple	A.R.	0,37	1,10	1,87	1,86	1,87	1,86	1,88
35	green apple	A.R.	0,33	1,01	1,81	1,81	1,82	1,83	1,84
36	green apple	A.R.	0,41	1,17	1,99	1,99	1,98	1,97	1,98
37	lavender	A.R.	0,36	1,16	1,86	1,86	1,87	1,86	1,87
38	lavender	A.R.	0,34	1,12	1,84	1,85	1,85	1,84	1,83
39	lavender	A.R.	0,35	1,19	1,97	1,98	1,97	1,96	1,97
40	black	A.R.	0,32	1,10	1,90	1,91	1,91	1,93	1,92
41	black	A.R.	0,37	1,18	1,99	1,97	1,97	1,96	1,96
42	black	A.R.	0,35	1,16	1,93	1,94	1,95	1,93	1,94
43	red	A.R.	0,34	1,18	1,90	1,91	1,92	1,91	1,93
44	red	A.R.	0,38	1,17	1,92	1,93	1,94	1,93	1,92
45	red	A.R.	0,36	1,15	1,91	1,90	1,91	1,92	1,90
Maximum permitted			**0,7**	**2,4**	**3,0**				

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

Jablonka St. 79.
1037 Budapest
HUNGARY

Tel.: +36-1 / 250-35-31
Fax: +36-1 / 430-08-88

E-mail: gepteszt@gepteszt.hu
web: www.gepteszt.hu

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: fullfillment 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.

……

Hajdu Márton
Head of the Inspection Body

2021.12.28.
issue date

2022.12.31.
expiry date

1037 Budapest
Jablonka út 79.
HUNGARY

Tel.: +36-1 / 250-35-31
Fax: +36-1 / 430-08-88

E-mail: gepteszt@gepteszt.hu
web: www.gepteszt.hu

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.

.....
Hajdu Márton
Head of the Inspection Body

GÉPTESZT Nº.: TD11/GT285/312/2104/E/2233

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

.....
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**
Issued:	**Budapest, 2021.04.29.**

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

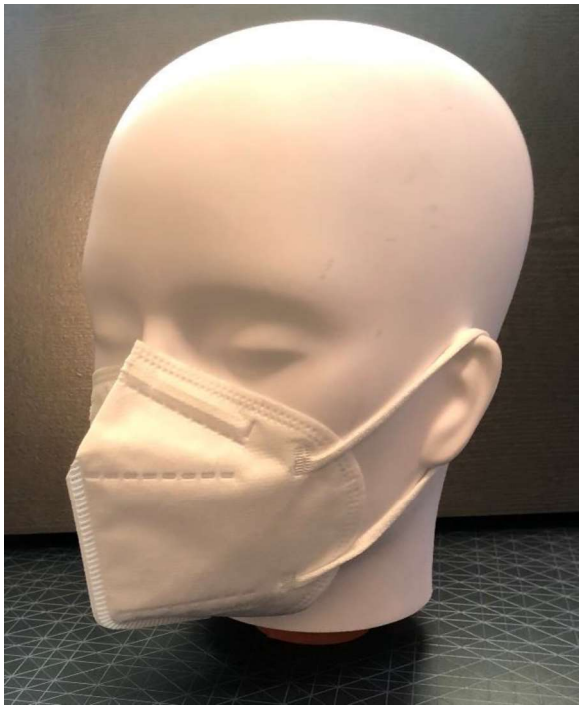
Budai Dániel
Director of Laboratory

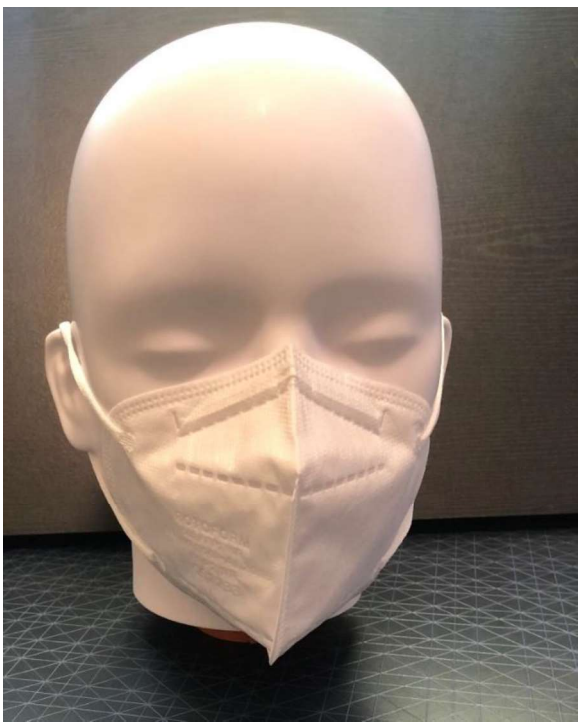
Relevant standards, directives and requirements:
EN 149:2001+A1:2009 Filtering half masks to protect against particles

Description of the sample
The 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 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 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 ± 0,2) m for 5 min;
   - crawling on the level with headroom of (0,70 ± 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/m^3, 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/m^3, 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 reistance, 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.

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

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INDUSTRIA POLIGRAFICA

Dichiarazione di conformità UE

PRODOTTO	MASCHERINA FFP2 NR DI TIPO IIR MONOUSO IN TNT AD ALTA TRASPIRABILITÀ CON ELASTICI
IDENTIFICATIVO ATTRIBUITO DAL FABBRICANTE (MODELLO/ PART NUMBER)	**MODELLO: 501 FFP2 NR TYPE IIR**
CONFORMITÀ CE	CE **2294763** **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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Cap. Soc. € 98.800,00 i.v. · P. IVA 02111231003 · Cod. Fisc. 08653830581 · C.C.I.A.A. 671019 · Iscr. Trib. 870/89

Certificato N. IT19-6704A
Certificato N. IT19-10801B
Certificato N. IT18-24701C

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Il marchio della gestione forestale responsabile

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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.

La **501 FFP2 NR 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, 03/09/2022

Nome: Tullio Di Virgilio

Posizione: Amministratore Unico

Per conto di: Rotoform Srl

Firma: _____

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Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante: **ROTOFORM**
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: **2294763**
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:29/01/2023

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	2294763	N	501 FFP2 NR	TYPE IIR 501 FFP2 NR	R030199 - MASCHERE RESPIRATORIE - ALTRE	D.L.vo 46/97 attuazione Dir. CE 93/42	I - Classe I non sterile e senza funzioni di misura	03/09/2022		FABBRICANTE	ROTOFORM S.R.L.	08653830581	02111231003	IT

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Indietro

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LEGENDA SIMBOLI INSERITI NELLE SCATOLE DELLE MASCHERINE MODELLO:

Modello: **501 FFP2 NR** nei seguenti colori:

BIANCO – NERO – VERDE SCURO – BORDO' – GLICINE – GIALLO – VERDE – ROSA – ARANCIONE – CICLAMINO- BLU – GRIGIO - VERDE MELA – LAVANDA – ROSSO.

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	<80%	Umidità massima di stoccaggio < 80%.
CE 2233	Marcatura CE + numero di identificazione univoca dell'Organismo Notificato coinvolto nella procedura di valutazione della conformità		

Roma, 09/02/2023

L'Amministratore unico - Di Virgilio Tullio

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