100% MADE IN ITALY

PROTECH

FASCICOLO TECNICO

- MODULO B
- MODULO C2
- CERTIFICAZIONE COLORI
- TEST REPORT
- SCHEDA TECNICA
- DICHIARAZIONE DI CONFORMITA’
- CHIARIMENTI & SPIEGAZIONI

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PROTECH

CE 2233

CERTIFICAZIONE MODULO B

FFP2 NR
DPI III CATEGORIA
MADE IN ITALY

GÉPTESZT Nº.: TD11/GT255/250/2102/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**
   Pro Tech FFP2 *FFP2 non reusable particle filtering half mask without valves.*
   Serial / Model No.: Pro Tech FFP2
   Year of production: 2021
2. Name and address of the holder of the certificate (Manufacturer or authorized representative):
   TECHPRINT SRL
   Address: Via Traversa di Maiano 11 / 16- 59100 Prato, 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: *VD35/255/2102/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The EU type-examination certificate will be withdrawn in case of existence of conditions stated in Article 32 point 5.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 24th February, 2026

Budapest, 24th February, 2021– HUNGARY

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

Budai István
Head of Certification Body

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PROTECH

CE 2233

CERTIFICAZIONE MODULO C2

FFP2 NR
DPI III CATEGORIA
MADE IN ITALY

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/E154/2102/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):

TECHPRINT SRL

Address: Via Traversa di Maiano 11 / 16- 59100 Prato, 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

2021.02.24.
issue date

2021.12.31.
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 inspection Via Traversa di Maiano 11 / 16- 59100 Prato, ITALY
Date of inspection: 2021.02.24.
Inspection report number: VD35/255/2102/E/2233

Annex 1 of N° ED29/E154/2102/E/2233

Description	Model/Type	EU type-examination certificate	Issued by
Particle filtering half-mask	Pro Tech FFP2	TD11/GT255/250/2102/E/2233	GÉPTESZT

Budapest, 2021.02.24.

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

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

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CE 2233

CERTIFICAZIONE COLORI

FFP2 NR
DPI III CATEGORIA
MADE IN ITALY

GÉPTESZT Nº.: TD11/GT255/250/2102/X1/E/2233

EU TYPE-EXAMINATION CERTIFICATE EXTENSION

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 extension is valid only with:

EU type-examination certificate No.: TD11/GT255/250/2102/E/2233
Record of examination No.: VD35/255/2102/E/2233 and VD36/255/X1/2102/E/223

The EU type-examination certificate is not transferable.

1. Product designation: **Particle filtering half mask**
   Pro Tech *FFP2 non reusable particle filtering half mask without valves in white, pink fuchsia, turquoise, green, beige, stain leopard, pink military, mimetic military and black colours.*
   Serial / Model No.: Pro Tech FFP2
   Year of production: 2021
2. Name and address of the holder of the certificate (Manufacturer or authorized representative):
   TECH PRINT SRL
   Address: Via Traversa di Maiano 11/ 16- 59100 Prato, 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: *VD35/255/2012/E/2233 and VD36/255/X1/2102/E/223*
   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 24th February, 2026

Budapest, 23rd March, 2021– HUNGARY

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

Budai István
Head of Certification Body

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PROTECH

TEST REPORT

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:	**TECHPRINT SRL** Address: Via Traversa di Maiano 11 / 16- 59100 Prato, ITALY
Model:	**Pro Tech FFP2**
Classification:	**FFP2 NR**
Exhalation valve:	**NO**
Inhalation valve:	**NO**
Uses:	**non reusable**
Project number:	**GT255**
Test report number:	**VD35/255/2102/E/2233**
Project worksheet number:	**VD-34-2021-255**
Date of the test:	**2021.02.12 - 02.26.**
Samples received date:	**2021.02.12.**
Sample numbers:	**255-1 - 255-46**
Attachment:	**no**

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

Issued: **Budapest, 2021.02.26.**

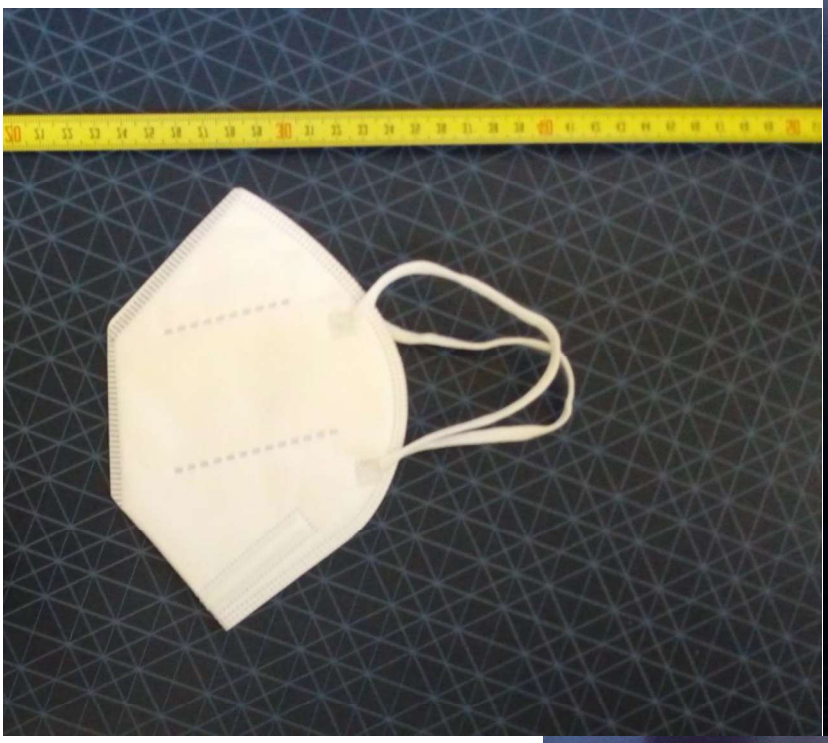
Budai Dániel
Director of Laboratory

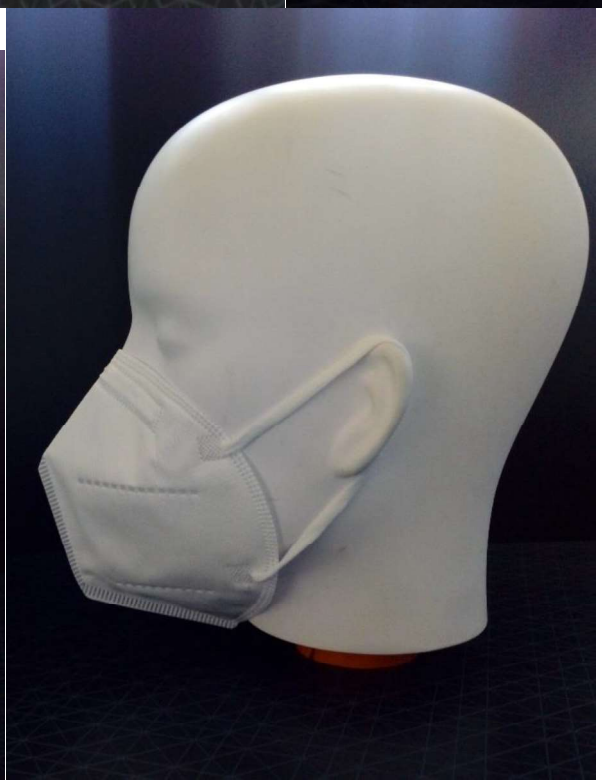
Relevant standards, directives and requirements:
EN 149:2001+A1:2009 Filtering half masks to protect against particles

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

1. TNT POLYESTER
2. MELTBLOWN Poliproplene
3. TNT 100% POLIPROPILENE
4. MELTBLOWN
5. TNT POLIPROPILENE 100%

The nose clip is made of PP. The elastic earloop is made of elastomere/nylon.





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 PVC bag, 10 pieces of masks are packed in a cardboard box.
The packaging gives enough protection against mechanical damage or contamination.
PASSED

7.5 Material
- conditioning S.W.: Sample nr: 255-16 to 255-18
  None of the particle filtering half masks have suffered mechanical failure of the facepiece or straps.
- conditioning T.C.: Sample nr.: 255-41 to 255-43
  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
BK	255-1	A.R.	PASSED
TLA	255-2	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**
LA	123	140	105	60
BL	110	140	130	50
SA	110	120	120	50
RE	115	138	112	48
BD	120	130	135	55
NA	130	120	130	50
DF	108	136	105	55
NT	122	134	142	57
BN	105	119	111	57
BP	120	125	116	57

Subject	**Sample**	**Cond.**	**Total inward leakage, %**					**Mean, %**
			Walk	**Head left/right**	**Head up/down**	**Talk**	**Walk**	
LA	255-3	A.R.	2,32	1,97	2,29	5,02	3,54	3,03
BL	255-4	A.R.	4,51	2,70	3,87	3,97	3,71	3,75
SA	255-5	A.R.	4,73	4,90	5,17	3,86	3,49	4,43
RE	255-6	A.R.	2,21	2,86	2,61	3,45	2,76	2,78
BD	255-7	A.R.	3,45	3,56	4,01	6,73	3,31	4,21
NA	255-8	T.C.	2,70	2,55	3,31	2,31	3,30	2,83
DF	255-9	T.C.	4,00	4,76	4,85	6,67	4,82	5,02
NT	255-10	T.C.	5,15	5,41	3,75	4,57	4,30	4,64
BN	255-11	T.C.	3,69	3,79	3,40	5,16	3,48	3,90
BP	255-12	T.C.	2,88	3,17	3,09	4,38	2,81	3,27

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, %**
255-13	A.R.	1,33	NA
255-14	A.R.	1,20	NA
255-15	A.R.	1,32	NA
255-16	S.W.	1,17	NA
255-17	S.W.	1,27	NA
255-18	S.W.	1,28	NA
255-19	**M.S→T.C.**	NA	1,29
255-20	**M.S→T.C.**	NA	1,37
255-21	**M.S→T.C.**	NA	1,28
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, %
255-22	A.R.	2,27	NA
255-23	A.R.	2,29	NA
255-24	A.R.	2,23	NA
255-25	S.W.	2,40	NA
255-26	S.W.	2,64	NA
255-27	S.W.	2,42	NA
255-28	**M.S→T.C.**	NA	2,96
255-29	**M.S→T.C.**	NA	3,12
255-30	**M.S→T.C.**	NA	2,99
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
255-33	T.C.
255-34	T.C.
255-31	A.R.
255-32	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%
255-35	0,52
255-36	0,54
255-37	0,49
Average	**0,52**

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
255-1
255-2

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		Exhalation reistance 160 l/min				
		30 l/min	95 l/min	ahead	vert.upwards	vert downwards	left	right
255-38	A.R.	0,38	1,19	1,92	1,94	1,92	1,93	1,92
255-39	A.R.	0,36	1,16	1,95	1,96	1,94	1,94	1,95
255-40	A.R.	0,37	1,15	1,93	1,94	1,94	1,93	1,93
255-41	T.C.	0,33	1,09	1,78	1,79	1,78	1,79	1,78
255-42	T.C.	0,34	1,08	1,81	1,81	1,80	1,81	1,81
255-43	T.C.	0,33	1,11	1,79	1,81	1,80	1,79	1,78
255-44	S.W.	0,35	1,10	1,83	1,84	1,83	1,82	1,83
255-45	S.W.	0,34	1,12	1,81	1,83	1,82	1,81	1,82
255-46	S.W.	0,36	1,11	1,84	1,84	1,84	1,82	1,83
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 **Pro Tech FFP2 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

100% MADE IN ITALY

PROTECH

SCHEDA TECNICA

Sede amministrativa	Via W. Tobagi – 59100 PRATO (PO)
Sede di progettazione	Via Fonda di Mezzana – 59100 PRATO (PO)
Sede Operativa	Via Traversa di Maiano 11 – 59100 PRATO (PO)

PRO TECH FFP2

TECHNICAL FILE

This Technical Documentation has been prepared according to the guidelines and contents of Annex III – Regulation (EU) 2016/425, with the aim of accompanying the certification by the appropriate Notified Body, following the compliance tests to EN 149:2001 - A1:2009.

SUBMITTED BY NAME:	Jianrui Cai
SUBMITTED BY DATE:	11/02/2021
STATEMENT:	**The signature below is to confirm that the statements, information and declarations within this technical file are true and accurate.**
SIGNATURE:	

General Information

MANUFACTURER NAME:	**TECH PRINT SRL**
MANUFACTURER ADDRESS:	**VIA TRAVERSA DI MAIANO 11/16 59100 PRATO (ITALY)**
	Sede Amministrativa: Via W. Tobagi 39– 59100 PRATO
PRODUCT TYPE:	**Half-Face RESPIRATOR**
APPLICABLE STANDARDS:	**EN 149:2001+A1:2009**
MODEL IDENTIFICATION:	**PRO TECH**
PERFORMANCE CLASSIFICATION:	**FFP2 NR**
TECHNICAL FILE REFERENCE:	**FASCICOLO TECNICO**
DATE AND REVISION CONTROL:	**Rev.00 del 11/02/2021**

Product Images

TABLE OF CONTENTS

1. AUTHORISED REPRESENTATIVE	
Authorised representative appointed?	NO
Company Name:	
Full Postal Address:	
DECLARATION **N/A**	
NAME:	**DATE:**

2. INTENDED USE OF THE PPE
PRO TECH FFP2 Pro, is a facial half-mask; no-valve, for professional and working use for one shift (8hrs). Classified as Personal Protective Equipment (PPE) category III, it is designed to protect the respiratory tract from contaminants and viruses.

3. TECHNICAL SPECIFICATION OR HARMONIZED STANDARDS *This section is split into two parts. (3.1) should be completed if a technical specification has been used, and (3.2) should be completed if harmonized standards have been used.*	
3.1 TECHNICAL SPECIFICATION *A technical specification is used typically where there is no appropriate harmonized standard, or there is a gap in harmonized standards requiring a technical specification to be produced. A technical specification can incorporate some clauses of harmonized standards. Where a technical specification has been used, please complete the below.*	
Technical specification used?	**NO**
Harmonized standard(s) clauses used?	**NO**
STANDARD NUMBER & DATE OF PUBLICATION	**CLAUSE NUMBERS USED**

3.2. HARMONIZED STANDARDS

Please list all of the harmonized standards applicable to the product to test conformity to the EHSRs and confirm if the standard has been used in full. If only some clauses of a standard have been applied, those clauses should be listed.

STANDARD & DATE	**FULL OR PART USED**	**CLAUSE NUMBERS USED**
EN 149:2001+A1:2009	Has been used in full?	

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
1	**GENERAL REQUIREMENTS APPLICABLE TO ALL PPE**					
	PPE must provide adequate protection against the risks against which it is intended to protect.	**YES**				
1.1	**Design principles**					
1.1.1	***Ergonomics***					
	PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.	**YES**				
1.1.2	***Levels and classes of protection***					
1.1.2.1	***Optimum level of protection***					
	The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.	**YES**				
1.1.2.2	***Classes of protection appropriate to different levels of risk***					
	Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.	**YES**				
1.2	**Innocuousness of PPE**					
1.2.1	***Absence of inherent risks and other nuisance factors***					
	PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.	**YES**				
1.2.1.1	***Suitable constituent materials***					
	The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.	**YES**				
1.2.1.2	***Satisfactory surface condition of all PPE parts in contact with the user***					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.	**YES**				
1.2.1.3	***Maximum permissible user impediment***					
	Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.	**YES**				
1.3	**Comfort and effectiveness**					
1.3.1	***Adaptation of PPE to user morphology***					
	PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.	**YES**				
1.3.2	***Lightness and strength***					
	PPE must be as light as possible without prejudicing its strength and effectiveness.	**YES**				
	PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.	**YES**				
1.3.3	***Compatibility of different types of PPE intended for simultaneous use***					
	If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.	**NO**				
1.3.4	***Protective clothing containing removable protectors***					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

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	Protective clothing containing removable protectors constitutes PPE and shall be assessed as a combination during conformity assessment procedures.	**NO**				
1.4	**Manufacturer's instructions and information**					
	In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:	**YES**				
	(a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;	**YES**				
	(b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;	**YES**				
	(c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;	**NO**				
	(d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;	**YES**				
	(e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;	**YES**				
	(f) where applicable, the type of packaging suitable for transport;	**YES**				
	(g) the significance of any markings (see point 2.12);	**YES**				
	(h) the risk against which the PPE is designed to protect;	**YES**				
	(i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;	**YES**				
	(j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;	**YES**				
	(k) references to the relevant harmonized standard(s) used, including the date of the standard(s), or references to the other technical specifications used;	**YES**				

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	(l) the internet address where the EU declaration of conformity can be accessed.	**YES**				
	The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.	**YES**				
2	**ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE**					
2.1	**PPE incorporating adjustment systems**					
	If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.	**NO**				
2.2	**PPE enclosing the parts of the body to be protected**					
	PPE must be designed and manufactured in a way that perspiration resulting from use is minimised. Otherwise it must be equipped with means of absorbing perspiration.	**NO**				
2.3	**PPE for the face, eyes and respiratory system**					
	Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.	**YES**				
	The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.	**NO**				
	If necessary, such PPE must be treated or provided with means to prevent misting-up.	**NO**				
	Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.	**NO**				
2.4	**PPE subject to ageing**					
	If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.	**YES**				

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	If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, **his instructions** must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.	**YES**				
	Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be NBted or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.	**NO**				
2.5	**PPE which may be caught up during use**					
	Where the foreseeable conditions of use include, in particular, the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must be designed and manufactured in such a way that a constituent part will break or tear, thereby eliminating the danger.	**NO**				
2.6	**PPE for use in potentially explosive atmospheres**					
	PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.	**NO**				
2.7	**PPE intended for rapid intervention or to be put on or removed rapidly**					
	Those types of PPE must be designed and manufactured in such a way as to minimise the time required for putting on and removing the equipment.	**NO**				
	Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate such systems quickly and easily.	**NO**				
2.8	**PPE for intervention in very dangerous situations**					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.	NO				
	The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.	NO				
	Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.	NO				
2.9	**PPE incorporating components which can be adjusted or removed by the user**					
	Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.	NO				
2.10	**PPE for connection to complementary equipment external to the PPE**					
	Where PPE incorporates a connexion system permitting its connection to other complementary equipment, the means of attachment must be designed and manufactured in such a way as to enable it to be mounted only on appropriate equipment.	NO				
2.11	**PPE incorporating a fluid circulation system**					
	Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed in such a way as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.	NO				
2.12	**PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety**					

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonized pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.	**NO**				
	Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.	**NO**				
2.13	**PPE capable of signalling the users presence visually**					
	PPE intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.	**NO**				
2.14	**Multi-risk PPE**					
	PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured in such a way as to satisfy, in particular, the essential health and safety requirements specific to each of those risks.	**NO**				
3	**ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS**					
3.1	**Protection against mechanical impact**					
3.1.1	***Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle***					

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	PPE intended to protect against this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the means of shock-absorption would preclude effective use of the PPE for the foreseeable period of wear.	**NO**				
3.1.2	***Falls***					
3.1.2.1	***Prevention of falls due to slipping***					
	The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means so as to ensure adequate grip, having regard to the nature or state of the surface.	**NO**				
3.1.2.2	***Prevention of falls from a height***					
	PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimised to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any PPE component which might cause the user to fall can be expected to occur.	**NO**				
	Such PPE must also ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary.	**NO**				
	The manufacturer's instructions must specify, in particular, all relevant information relating to:	**NO**				
	(a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user;	**NO**				
	(b) the proper way of putting on the body harness and of attaching the connexion system to the reliable external anchorage point.	**NO**				
3.1.3	***Mechanical vibration***					

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.	**NO**				
3.2	**Protection against static compression of a part of the body**					
	PPE designed to protect a part of the body against static compressive stress must be sufficiently capable of attenuating its effects so as to prevent serious injury or chronic complaints.	**NO**				
3.3	**Protection against mechanical injuries**					
	PPE constituent materials and other components designed to protect all or a part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be chosen or designed and incorporated so as to ensure that those types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also point 3.1) under the foreseeable conditions of use.	**NO**				
3.4	**Protection in liquids**					
3.4.1	***Prevention of drowning***					
	PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping the user afloat in a position which permits breathing while awaiting help.	**NO**				
	PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or inflated orally.	**NO**				
	Under the foreseeable conditions of use:	**NO**				
	(a) PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium;	**NO**				
	(b) inflatable PPE must be capable of inflating rapidly and fully.	**NO**				
	Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:	**NO**				

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	(a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device;	**NO**				
	(b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;	**NO**				
	(c) they must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring the user's immersion in it.	**NO**				
3.4.2	***Buoyancy aids***					
	Clothing intended to ensure an effective degree of buoyancy, depending on its foreseeable use, shall be safe when worn and afford positive support in the liquid medium. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable the user, in particular, to swim or take action to escape from danger or to rescue other persons.	**NO**				
3.5	**Protection against the harmful effects of noise**					
	PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not exceed the limit values laid down by Directive 2003/10/EC of the European Parliament and of the Council (1).	**NO**				
	Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE. Should that not be possible, the labelling must be fixed to the packaging.	**NO**				
3.6	**Protection against heat and/or fire**					
	PPE designed to protect all or a part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to the foreseeable conditions of use.	**NO**				
3.6.1	***PPE constituent materials and other components***					

	Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to	**NO**				
		YES /NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Where the external surface of those materials and components must be reflective, the reflective power must be appropriate to the intensity of the heat flux due to radiation in the infrared range.	**NO**				
	Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed the PPE.	**NO**				
	PPE materials and other components which may be splashed by hot products must also possess sufficient mechanical-impact absorbency (see point 3.1).	**NO**				
	PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of industrial or fire-fighting equipment must also possess a degree of non-flammability and thermal or arc heat protection corresponding to the risk class associated with the	**NO**				
3.6.2	Complete PPE ready for use					

	Under the foreseeable conditions of use:	**NO**				
	(a) the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;	**NO**				
	(b) PPE must, if necessary, prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.	**NO**				
	If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, the design of such devices must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.	**NO**				
	If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.	**NO**				

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	The manufacturer's instructions accompanying PPE intended for brief use in high-temperature environments must, in particular, provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.	**NO**				
3.7	**Protection against cold**					
	PPE designed to protect all or a part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is intended.	**NO**				
3.7.1	***PPE constituent materials and other components***					
	Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.	**NO**				
	PPE materials and other components which may be splashed by cold products must also possess sufficient mechanical-impact absorbency (see point 3.1).	**NO**				
3.7.2	***Complete PPE ready for use***					
	Under the foreseeable conditions of use, the following requirements apply:	**NO**				
	(a) the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health impairment threshold;	**NO**				
	(b) PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.	**NO**				
	If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.	**NO**				

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	The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.	**NO**				
3.8	**Protection against electric shock**					
3.8.1	***Insulating equipment***					
	PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.	**NO**				
	To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimised and, in any event, below a maximum conventional permissible value which correlates with the tolerance threshold.	**NO**				
	Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class or corresponding operating voltage, their serial number and their date of manufacture. A space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or NBtions to be conducted.	**NO**				
	The manufacturer's instructions must indicate, in particular, the exclusive use for which those PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.	**NO**				
3.8.2	***Conductive equipment***					
	Conductive PPE intended for live working at high voltages shall be designed and manufactured in such a way as to ensure that there is no difference of potential between the user and the installations on which he is intervening.	**NO**				

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3.9	**Radiation protection**					
3.9.1	***Non-ionising radiation***					
	PPE designed to prevent acute or chronic eye damage from sources of non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.	**NO**				
	To that end, eye protective equipment must be designed and manufactured so as to possess, for each harmful wavelength, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimised and under no circumstances exceeds the maximum permissible exposure value. PPE designed to protect the skin against non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths.	**NO**				
	Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.	**NO**				
	Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use such as the distance from the source and the spectral distribution of the energy radiated at that distance.	**NO**				
	The relevant protection factor number must be marked on all specimens of filtering eye protective equipment by the manufacturer.	**NO**				
3.9.2	***Ionising radiation***					
3.9.2.1	***Protection against external radioactive contamination***					

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	PPE constituent materials and other components designed to protect all or a part of the body against radioactive dust, gases, liquids or mixtures thereof must be chosen or designed and incorporated so as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.	**NO**				
	Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurisation systems designed to prevent the back-scattering of these contaminants.	**NO**				
	Any decontamination measures to which PPE is subject must not prejudice its possible reuse during the foreseeable useful life of those types of equipment.	**NO**				
3.9.2.2	***Protection against external irradiation***					
	PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation.	**NO**				
	The constituent materials and other components of these types of PPE must be chosen or designed and incorporated so as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see point 1.3.2).	**NO**				
	PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.	**NO**				
3.10	**Protection against substances and mixtures which are hazardous to health and against harmful biological agents**					
3.10.1	***Respiratory protection***					
	PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.	**NO**				

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.	**NO**				
	The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.	**NO**				
	The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.	**NO**				
	The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.	**NO**				
	In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.	**NO**				
3.10.2	***Protection against cutaneous and ocular contact***					
	PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.	**NO**				
	To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.	**NO**				

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.	**NO**				
3.11	**Diving equipment**					
	The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.	**NO**				
	Where the foreseeable conditions of use so require, the diving equipment must comprise the following:	**NO**				
	(a) a suit which protects the user against cold (see point 3.7) and/or pressure resulting from the depth of immersion (see point 3.2);	**NO**				
	(b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see point 2.8);	**NO**				
	(c) a lifesaving device enabling the user to return to the surface (see point 3.4.1).	**NO**				

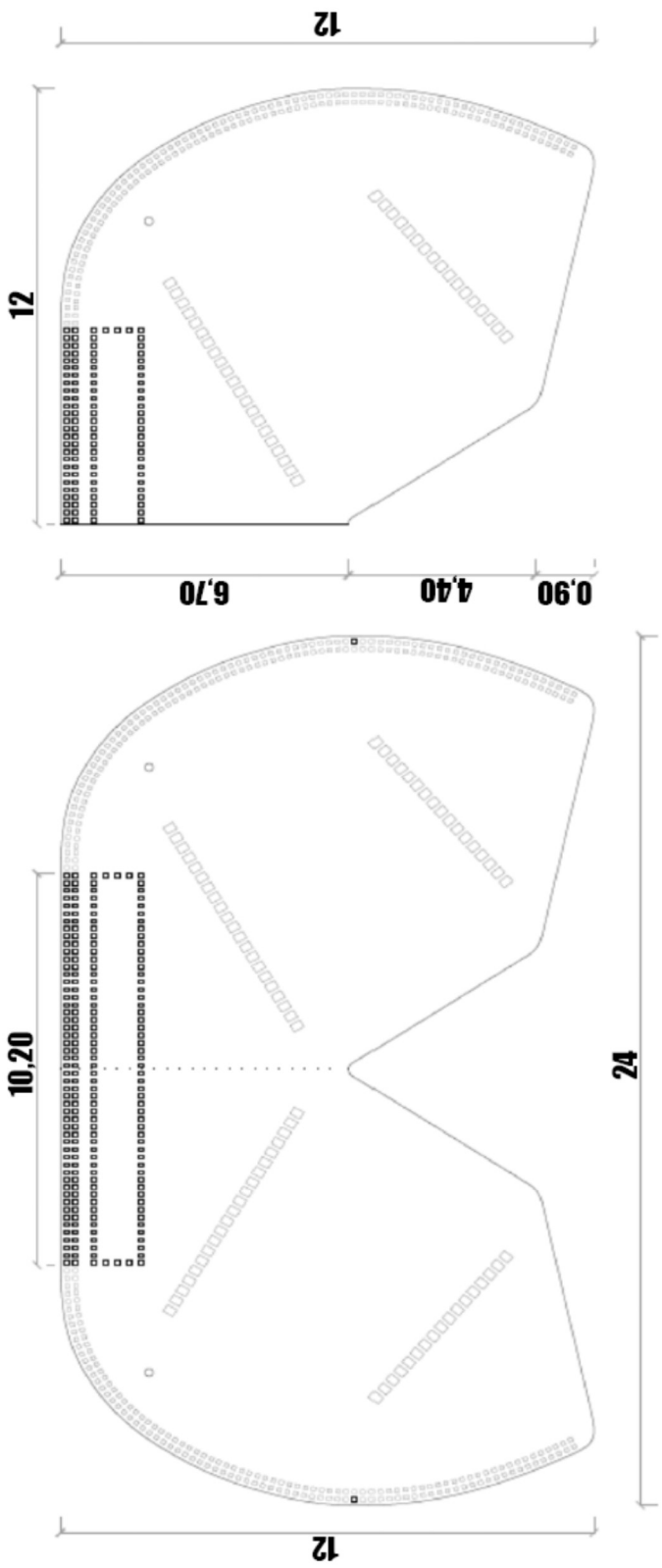
5. RISK ASSESSMENT

The risk assessment should identify any other risks not already covered by the EHSRs, based on the intended use of the product. Please include a risk assessment statement. If there are no additional risks the statement should confirm this. If there are additional risks, please describe the risk; the action taken may be either testing/user info or marking and you need only mark this with an 'X'. If the action is 'other' please briefly describe the action taken.

Tech Print Srl have undertaken a risk assessment of theproduct(s) considering the intended use, and the possibility of mis-use. Our product is Filtering half mask and intended to protect against particles and dust and we have not identified any additional risks, not already addressed by the Essential Health & Safety Requirements of the PPE Regulation.

SPECIFIC RISKS	ACTIONS TAKEN TO ADDRESS (Mark with X)			
Description of risk	TEST	USER INFO	MARKING	OTHER (DESCRIBE)
N/A				

6. DESIGN AND MANUFACTURING DRAWINGS



7. COMPONENTS MATERIALS:

The mask is made of 5 layers, to ensure enhanced performances, composed by the followings (from outside to the face):

- **- TNT POLYESTER 60 GR/MQ (Strato esterno) NONTEX SRL**
- **- MELTBLOWN 25 GR/MQ 100%Fibrille di Polipropilene (PP) R.S. di Zhang Xhue Chai**
- **- TNT 100% POLIPROPILENE 30 GR/MQ NORTEX SRL e Zhang Xhue Chai**
- **- MELTBLOWN 25 GR/MQ di Zhang Xhue Chai**
- **- TNT POLIPROPILENE 100% 60 GR/MQ (Strato interno) nontex Srl**

In addition to the 5 layers of fabric, other components of the mask are:

- **Elastico 3 mm 70% elastomero e 30% nylon di GB Filati**
  Stringinaso 0,67 mm PP di Nerini Spa

COMPONENT OR SUB-COMPONENT	MATERIAL	GRADE	EXTERNALLY SOURCED

MATERIAL DECLARATION	
	
NAME: Jianrui Cai	**DATE: 11/02/2021**
MARK 'X' INSIDE THE BOX TO CONFIRM THE DECLARATION IS TRUE AND VALID ☒	

7.1 PRODUCT TO BE FITTED TO ANOTHER MANUFACTURER'S PRODUCT

This section is applicable if your product is designed to be used with another manufacturer's product, e.g. a helmet-mounted earmuff. In this case, you will need to provide evidence that you have an agreement with the applicable manufacturer(s) to use their product during testing, and that they will advise of any design changes to their products, or any issues with production, e.g. product recalls.

Attachments listed below should be sent with the completed technical file

Does your product rely on another manufacturers product to be used as a complete PPE?	**NO**	
MANUFACTURER NAME	**DOCUMENT TITLE & ISSUE/REVISION STATUS**	**ATTACHED?**

7.2 SPARE PARTS & ACCESSORIES

This section is applicable if you supply spare and accessories for the certified product. Please list the part and confirm the type, and where the spare part of accessory is listed. If spare parts and accessories are listed on a separate sheet to the user information, the sheet should be supplied with the technical file.

Does your product have spare parts or accessories available?	**NO**	
DESCRIPTION	**TYPE?**	**DETAILED IN?**

8. USER INFORMATION DOCUMENT

PROTECH

ITA istruzioni EN149:2001+A1:2009 FFP2 NR

1. Lava accuratamente le mani con acqua e sapone o con disinfettante a base di alcol prima di indossare la mascherina.
2. Indossa la mascherina impugnandola dagli elastici laterali.
3. Nel coprire la bocca ed il naso, assicurati che non ci siano spazi tra il viso e la mascherina in modo che aderisca bene al volto.
4. Evita di toccare la macherina durante l'uso e sostituiscila con una nuova non appena è umida.
5. Rimuovi la mascherina dalla estremità laterali senza toccare la parte anteriore.
6. Subito dopo l'uso buttala in un apposito contenitore.
7. Lava subito le mani con acqua e sapone o gel igenizzante.
8. La maschera filtrante non deve essere usata per più di un turno.
9. Controllare prima di indossare
10. È improbabile che i requisiti per le perdite vengano raggiunti se i peli del viso passano sotto il sigillo facciale
11. Non utilizzare in presenza di carenza di ossigeno o in atmosfera contaminante
12. Non usare in atmosfera esplosiva
13. La semimaschera di filtraggio delle particelle non deve essere utilizzata per più di un turno
14. Non utilizzare la semimaschera filtrante per particelle per più di 8 ore

ENG Instructions EN149:2001+A1:2009 FFP2 NR

1. Wash your hands thoroughly with water or alcohol-based disinfectant before putting on the mask.
2. Wear the mask gripping it by the side elastics.
3. When covering the mouth and nose, make sure there are no spaces between the face and the mask so that it fits snugly to the face.
4. Avoid touching the mask during use and replace it with new one as soon as it is wet.
5. Remove the mask from the side ends without touching the front.
6. Immediately after use, throw it in a special container.
7. Wash your hands immediately with soap and water or sanitizing gel.
8. The filtering half mask shall not be used for more than one shift.
9. Check prior to use
10. It is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal
11. Don't use if there is oxygen deficiency or in contaminant atmosphere
12. Don't use in explosive atmosphere
13. The particle filtering half mask shall not be used for more than one shift
14. Don't use the particle filtering half mask for more than 8 hours

DE Anleitung FFP2 NR

1. Waschen Sie Ihre Hände gründlich mit Wasser oder Desinfektionsmittel auf Alkoholbasis, bevor Sie die Maske aufsetzen.
2. Tragen Sie die Maske an den seitlichen Gumminbändern.
3. Achten Sie beim Abdecken von Mund und Nase darauf, dass zwischen Gesicht und Maske keine Zwischenräume vorhanden sind damit sie genau ins Gesicht passen.
4. Berühren Sie die Maske während des Gebrauchs nicht und ersetzen Sie sie durch eine neue, sobald sie nass ist.
5. Entfernen Sie die Maske von den Seitenenden, ohne die Vordseite zu berühren.
6. Werfen Sie es sofort nach Gebrauch in einen speziellen Behälter.
7. Waschen Sie Ihre Hände sofort mit Wasser und Seife oder Desinfektionsgel.
8. Die filternde Halbmaske darf nicht für mehr als eine Schicht verwendet werden.
9. Vor Gebrauch überprüfen
10. Es ist unwahrscheinlich, dass die Anforderungen an die Leckage erfüllt werden, wenn das Gesichtshaar unter der Gesichtsversiegelung verläuft

8. USER INFORMATION DOCUMENT

11. Nicht verwenden, wenn Sauerstoffmangel vorliegt oder sich in einer kontaminierenden Atmosphäre befindet
12. Nicht in explosionsgefährdeten Bereichen verwenden
13. Die Partikelfilter-Halbmaske darf nicht länger als eine Schicht verwendet werden
14. Verwenden Sie die Partikelfilter-Halbmaske nicht länger als 8 Stunden

FR Instructions EN149:2001+A1:2009 FFP2 NR

1. Lavez-vous soigneusement les mains avec de l'eau ou avec un désinfectant à base d'acool avant de mettre le masque.
2. Mettre le masque en le tenant par les élastiques latéraux.
3. Lorsque vous couvrez la bouche et le nez, assurez-vous qu'il n'y a pas d'espace entre le visage et le masque afin qu'il s'adapte parfaitement au visage.
4. Évitez de toucher le masque pendant l'utilisation et remplacez-le par un neuf dès qu'il est mouillé.
5. Enlever le masque des extrémités latérals sans toucher le devant.
6. Immédiatement après utilisation, jetez-le dans un récipient spécial.
7. Lavez-vous immédiatement les mains avec du savon et de l'eau ou un gel désinfectant.
8. Le demi-masque filtrant ne doit pas être utilisé pendant plus d'un quart de travail.
9. N'utilisez pas le demi-masque filtrant les particules pendant plus de 8 heures
10. Il est peu probable que les exigences en matière de fuite soient satisfaites si les poils du visage passent sous le joint facial
11. Ne pas utiliser en cas de carence en oxygène ou dans une atmosphère contaminante
12. Ne pas utiliser dans une atmosphère explosive
13. Le demi-masque filtrant les particules ne doit pas être utilisé pendant plus d'un quart de travail
14. N'utilisez pas le demi-masque filtrant les particules pendant plus de 8 heures

ESP Instrucciones EN149:2001+A1:2009 FFP2 NR

1. Lávese bien las manos con agua o desinfectante a base de alcohol antes de ponerse la mascarilla.
2. Lleva la máscara sujetándola por los elásticos laterales.
3. Al cubrir la boca u y la nariz, asegúrese de que no queden espacios entre el rostro y la mascarilla para que se ajuste perfectamente al rostro.
4. Evite tocar la mascarilla durante el uso y reemplácela por una nueva tan pronto como esté mojada.
5. Retirar la mascarilla de los extremos laterales sin tocar la parte delantera.
6. Inmediatamente después de su uso, tírelo en un recipiente especial.
7. Láse les manos inmediatamente con agua y jabón o gel desinfectante.
8. La media máscara de filtrado no se utilizará para más de un turno.
9. No utilice la media máscara con filtro de partículas durante más de 8 horas.
10. Es poco probable que se cumplan los requisitos de fugas si el vello facial pasa por debajo del sello facial
11. No utilizar en caso de deficiencia de oxígeno o en una atmósfera contaminante.
12. No utilizar en una atmósfera explosiva.
13. La media máscara de filtrado de partículas no debe utilizarse durante más de un turno.
14. No utilice la media máscara con filtro de partículas durante más de 8 horas.

CE 2233
EN149:2001+A1:2009
FFP2 NR

produced by
Tech Print

8.1 DECLARATION – MATERIALS FOR MAINTENANCE, CLEANING AND DISINFECTING

MARK 'X' INSIDE THE BOX TO CONFIRM THE DECLARATION IS TRUE AND VALID ☐

8.2 DECLARATION – SUPPLY OF USER INFORMATION We declare that the user information accompanies each smallest commercially available unit.
MARK 'X' INSIDE THE BOX TO CONFIRM THE DECLARATION IS TRUE AND VALID □

9. PRODUCT MARKING

ON EACH MASK

FFP2 NR EN 149:2001+A1:2009

CE 2233

LOT 0121 M5 01

ON THE PACKET

TECH PRINT SRL

FFP2 NR

EN 1492001+A1:2009 e REG. EU 425/2016

LOT 0121 M5 01

CE 2233

1. Check prior to use
2. It is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal
3. Don't use if there is oxygen deficiency or in contaminant atmosphere
4. Don't use in explosive atmosphere
5. The particle filtering half mask shall not be used for more than one shift
6. Don't use the particle filtering half mask for more than 8 hours

9.1 PACKAGING MARKING

- Masks are individually packed into PVC bag.
- Masks are sold in carton box containing 10 pieces each.

Modello: FFP2 NR

Prodotto in Italia

PREMIUM QUALITY

Made in Italy

Standard EN 149:2001+A1:2009, Reg EU 425/2016

Queste mascherine soddisfano i requisiti
del regolamento UE 2016/425
Sono state testate secondo la norma
UNI EN 149:2001+A1:2009

NOTA INFORMATIVA
Verificare che la mascherina e tutti i suoi componenti
non presentino fori, strappi o altri danni.
In caso di danni non utilizzare.
Prodotto monouso.

AVVERTENZE PER L'USO
Conservare il prodotto in luogo fresco e asciutto.
Evitare l'esposizione diretta alla luce del sole,
all'ozono e a fonti di calore.
Dispositivo monouso: l'eventuale pulizia e/o sterilizzazione può
danneggiare il dispositivo. Smaltire in conformità delle normative
vigenti, il fabbricante declina ogni responsabilità per eventuali danni
derivanti da un utilizzo non conforme e/o improprio.

ATTENZIONE
La maschera, l'archetto del naso e l'elastico devono essere integri.
La maschera non deve essere lavata e non deve essere modificata
e/o manomessa.

5 LAYERS FFP2 MASK - NR

INFORMATION NOTE
Ensure that the mask and all its components do not have tears or other
damages.
In case of damage do not use.
The code 'NR' means that this is a disposable product, which must be
discarded at the end of work shift.

USER DIRECTIONS
Store the product in a cool and dry place in its own trasparent bag.
Avoid direct exposure to sunlight, ozone and heat sources.
Disposable mask: Any cleaning and/ or sterilization

Dispose of in accordance with current regulations
The manufacturer declines all responsability for any damage derived from
non- compliant or improper use.

ATTENTION
The mask, the bow of the nose and elastic must be intact.
The mask should not be tamp

Prodotto da TECH PRINT Srl
59100 Prato (PO)

2024/2 | <65% | +5° max +38°

EN 149:2001 + A1:2009
Tech Print s.r.l.

FFP2 SCHUTZ MASKEN NR - 5 SCHICHTEN
Informativer Hinweis

Überprüfen Sie die Masken und alle ihre Komponenten auf Risse, Löcher oder andere Beschadigungen. Im Schadensfall nicht verwenden.
Die Bezeichnung NR gibt an, dass es sich um ein Einwegprodukt handelt, das am Ende der Arbeischicht entsorgt werden muss.

Warnhinweise zur Verwendung
Lagern Sie das Produkt an einem kühlen und trockenen Ort in seiner transparenten Verpackung.
Vermeide Sie direkte Sonneneinstrahlung, Ozon und andere Wärmequellen
Einwegprodukt: Reinigung und/ oder Sterilisation können das Produkt beschadigen. In Übereinstimmung mit den geltenden Vorschrift enstorgen, der Hersteller lehnt jegliche Verantwortung für Schäden ab, die durch nicht konforme und/ order unsachgemäße Verwendung entstehen.

Vorsicht
Die Maske, das Nasenband und das Gummiband müssen intakt sein.
Die Maske darf nicht gewashen und nicht verandert und/ oder manipuliert werden.

MASQUE FFP2 NR - 5 STRATES

Note d'information
Assurez- vous que le masque et tous ses composants n'ont pas de déchirures, trous ou d'autres dommages.
En cas de dommage , n'utilisez pas
NR indique qu'il s'agit d'un produit à usage unique qui doit etrê jeté à la fin du tour de service.

Avertissements d'utilisation
Conserver le produit dans un endroit frais et sec dans son sachet transparent.
Évitez l'exposition directe à la lumière du soleil, sources d'ozone et de chaleur
Dispositif jetable: tout nettoyage et/ ou stérilisation peut endommager le dispositif.
Disposer conformément à la réglementation en vigueur, le fabricant décline toute responsabilité pour toute dommages résultant d'une utilisation non conforme et/ ou incorrecte.

Attention
Le masque, le bandeau avant et la bande élastique doivent etrê intacts
Le masque ne doit pas etrê lavé et ne doit pas etre modifié et/ ou altéré.

MASCARILLAS FFP2 - 5 CAPAS

Nota informativa
Verificar que la mascarilla y todos sus componentes no presentan rasgaduras, agujeros u otros daños.
En caso de daños no utilizar.
La sigla NR indica que se trata de un producto desechable, que debe eliminarse al término del turno de trabajo.

Advertencia para su uso
Conservar el producto en lugar fresco y seco, en una bolsa transparente.
Evitar la exposición directa a la luz del sol, al ozono y fuentes de calor.
Dispositivo desechable: la possible limpieza y/o esterilizaciones puede danär el dispositivo.
Desechar de acuerdo con las normativas vigentes, el fabricante declina toda responsabilidad por los eventuales daños derivados de un uso no conforme y/o improprio.

Atención
La mascarilla, el arco de la nariz y el elástico deben estar intactos.
La mascarilla no debe ser lavada y no debe ser modificada y/o manipulada.

10. **EU DECLARATION OF CONFORMITY**

DECLARATION OF CONFORMITY EU NR. 001

in acording to EN 149:2001+A1:2009 e Reg EU 425/2016

CE

The manufacturer

Tech Print

TECHPRINT SRL UNIPERSONALE
Address : Via W. Tobagi, 7 - 59100 Prato (PO)
PEC address: techprintsrl@pec.it

Declares under its own responsibility that Personal Protective Equipment described here after

Name	**HALF-FACE RESPIRATOR - Foldable disposable respirator**
STANDARDS	EN 149:2001+A1:2009
CLASS	Personal Protective Equipment (PPE) category III
Model	**PRO-TECH FFP2 NR - Lot 0121 M5 01**
Year of construction	2021

CE 2233

Conformity to type based on Module B + C2 under surveillance of Notify Body Gep Teszt N.2233

Devices are compliant with:

STANDARDS	EN 149:2001+A1:2009

Prato, February 23rd 2021

TECH PRINT S.r.l. Unipersonale
sede leg.: Via W. Tobagi, 49 PRATO
sede op.: Via delle Fonti, 354/6 PRATO
C.F. e P.I. 02302860974

11. TEST REPORTS FOR TYPE EXAMINATION

Each test report used for certification should be listed and attached here.

Attachments listed below should be sent with the completed technical file

TEST REPORT NUMBER	TEST HOUSE NAME	ATTACHED?

TECHNICAL DATA SHEETS OF THE RAW MATERIALS USED (for a better view, the data sheets are also included in the external annex)

Nontex 60 gr

NONTEX S.p.A.
NONWOVENS

TECHNICAL DATA FOR MOPET POLYESTER SPUNBOND FABRICS (POINTBOND)

NONTEX S.p.A.
02 / 04.11.2015

PROPERTIES	TEST METHOD	UNIT		/POINTBOND																								
WEIGHT	NWSP 130.1.R0 (15)	g/sq.m		17	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	100	110	120	130	140	150	160	180
THICKNESS	NWSP 120.6.R0 (15)	mm		0,1	0,12	0,13	0,15	0,17	0,19	0,21	0,23	0,25	0,27	0,29	0,3	0,31	0,32	0,34	0,35	0,36	0,38	0,4	0,44	0,46	0,49	0,5	0,51
TENSILE STRENGTH	NWSP 110.4.R0 (15)	N/5 cm	MD	34	40	50	60	80	100	110	130	140	150	160	210	225	240	255	270	300	330	340	350	370	400	420	470
			CD	14	17	25	35	40	50	50	65	70	75	75	100	111	120	140	160	180	200	210	220	230	250	260	290
ELONGATION	NWSP 110.4.R0 (15)	%	MD	18	20	20	22	26	28	29	30	32	33	34	35	36	37	38	39	40	42	43	44	43	42	38	38
			CD	23	26	27	30	32	34	34	34	36	37	38	41	42	43	44	45	46	47	48	49	50	52	50	50
AIR PERMEABILITY	NWSP 70.1.R0 (15)	l/m²/sn	100Pa	4580	3824	3117	2740	2452	2068	1536	1426	1294	1122	1050	885	819	782	728	670	633	530	419	341	301	278	260	240
MEAN FLOW PORE DIAMETER	ASTM D4752	micron		61	59	54	51	49	48	47	46	46	45	44	44	43	43	42	41	40	39	37	35	34	33	32	30
BURST STRENGTH	NWSP 30.2.R0 (15)	kpa		35	45	60	80	100	120	150	200	220	250	270	290	310	350	400	450	470	490	510	530	560	600	700	960
GURLEY STIFFNESS	NWSP 90.2.R0 (15)	mg	MD	1,9	3	4,4	6	10	22	30	40	50	51	56	60	70	76	85	90	100	140	210	280	370	400	500	700
			CD	3,5	5,8	8	12	21	30	40	60	65	77	84	90	100	110	130	140	150	190	310	400	550	600	720	100
TEAR STRENGTH	NWSP 100.2.R1 (15)	N	MD	10	13	17	23	25	28	29	30	34	36	38	42	44	48	50	52	56	61	65	69	80	95	102	110
			CD	15	20	25	29	35	36	39	42	44	45	48	56	59	61	63	67	74	84	89	92	98	107	120	140

- Masks are individually packed into PVC bag.
- Masks are sold in carton box containing 10 pieces each.

R.s. meltblown 25 gr 60 gr

R.S. di Zhang Xue Chai

Via Fonda di Mezzana, 59/D

59100 PRATO

P.I. 02283920979

CF ZHN XCH 62M64 Z210L

Prato, 10 Dicembre 2020

Tipologia prodotto	TNT MELTBLOWN
Composizione	100%Fibrille di Polipropilene (PP) Caricato elettrostaticamente

CARATTERISTICHE TECNICHE

	Unità	Metodo analisi	Valore
	gr/mq	UNI EN 29073-1	25 + / - 5%
	mm	ISO 9073-2	0,25 - 0,35
	l/m2 / sec	EN-ISO 9237 (200Pa, 20 cm2)	360 - 470
Diametro fibrille	um		1 - 3

Nontex 30 gr

N O N T E X S. P. A.
Via R. Scarpettini, 371 59013 Montemurlo (PO)
e-mail: info@nontex.it url: www.nontex.eu
P. I V A & C. F.: IT 01617060973 R E A n° 444714
CCIAA Prato Iscrizione Tribunale di Prato n° 18719
Cap. Soc. € 1.000.000 i.v.

Montemurlo, 01/04/20

SCHEDA TECNICA DEL TESSUTO NON TESSUTO
TECHNICAL DATA SHEET SPUNBOND - NON WOVEN

	PESO WEIGHT	RESISTENZA ALLA TRAZIONE TENSILE STRENGHT		ALLUNGAMENTO ALLA ROTTURA ELONGATION AT BREAK		RESISTENZA ALLO STRAPPO TEAR STRENGTH	
METODO METHOD		EDANA 20.2 - 89		EDANA 20.2 - 89		EDANA 20.2 - 89	
UNITA' UNIT	gr/m2	N/5cm	N/5cm	%	%	N	N
DIREZIONE DIRECTION	-	MD	CD	MD	CD	MD	CD
VALORI TIPICI TYPICAL VALUE	30	55,00	41,00	60,00	63,00	23,00	29,00

Il tessuto non tessuto è composto da 100% polipropilene. / The composition of spunbonded is 100% polypropylene.

Contatto con il Cibo/Alimenti : Il regolamento UE n°10/2011 sui materiali destinati a venire a contatto con gli alimenti all'art 12 dice che un materiale da imballo non deve rilasciare più di 10 mg/dmq. Il nostro prodotto rilascia 1,5 mg/dmq, è dunque conforme ai limiti di legge. Contact with Food / Aliments: The EU regulation No. 10/2011 on materials intended to come into contact with food all 12 nuts that a packaging material must not be released more than 10 mg / dmq. Our product releases 1.5 mg / dmq, therefore it complies with the legal limits.

Nontex Spa dichiara che i nostri prodotti non contengono alcuna sostanza presente nell'elenco di sostanze candidate estremamente preoccupanti per l'autorizzazione, aggiornato il 16 gennaio 2020 al di sopra della soglia dello 0,1% stabilita dal regolamento 1907/2006 / CE (REACH).
Nontex Spa declares that our products do not contain any substance presents in the Candidate List of Substances of Very High Concern for authorization, as updated on January 16th 2020 above the 0.1% threshold as stated in the Regulation 1907/2006/EC (REACH).

Il tessuto non tessuto è Idrorepellente // Nonwoven fabric is Hydrophobic

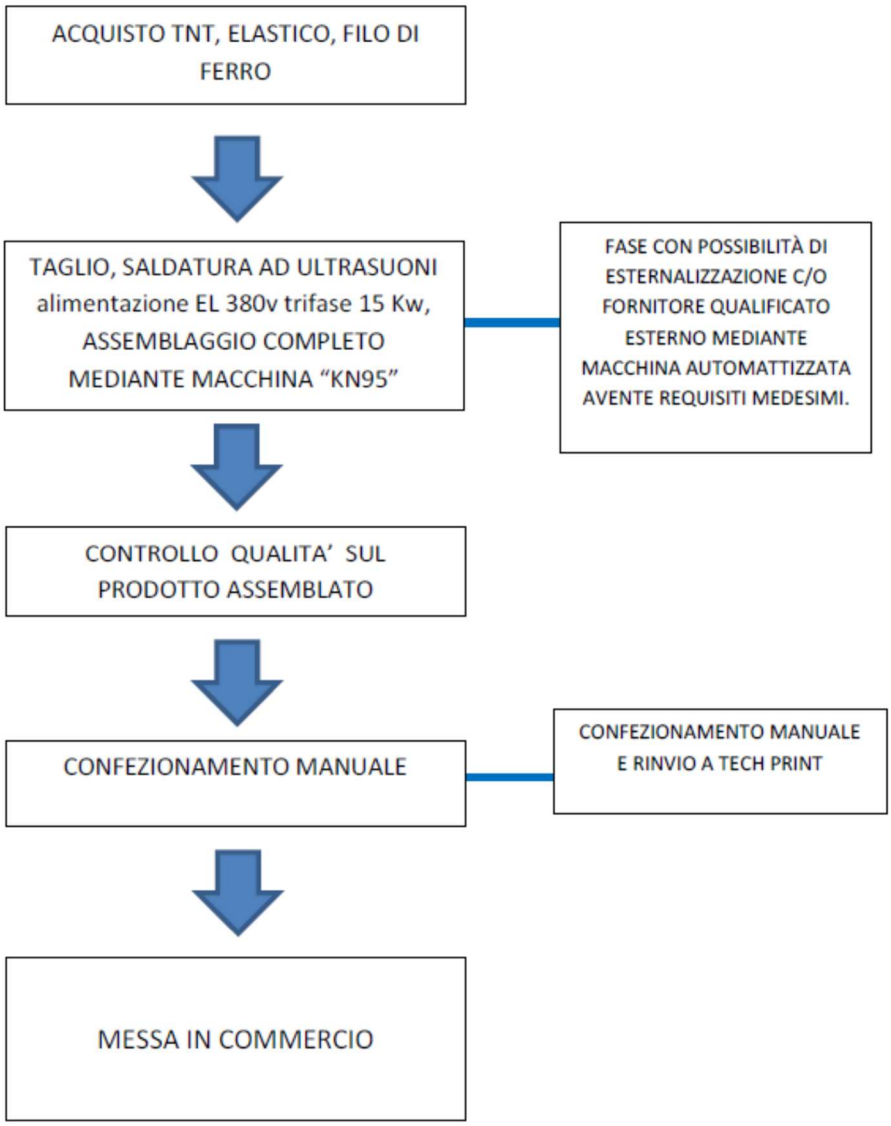
I materiali forniti sono di origine preferenziale C.E.E. (Comunità Europea) / The supplied materials are of preferential origin C.E.E.

Questa dichiarazione è applicabile al tessuto non tessuto bianco così come da noi fornito./ This declaration is applicable to our white non-woven fabric as supplied by us

Production FLOW CHART

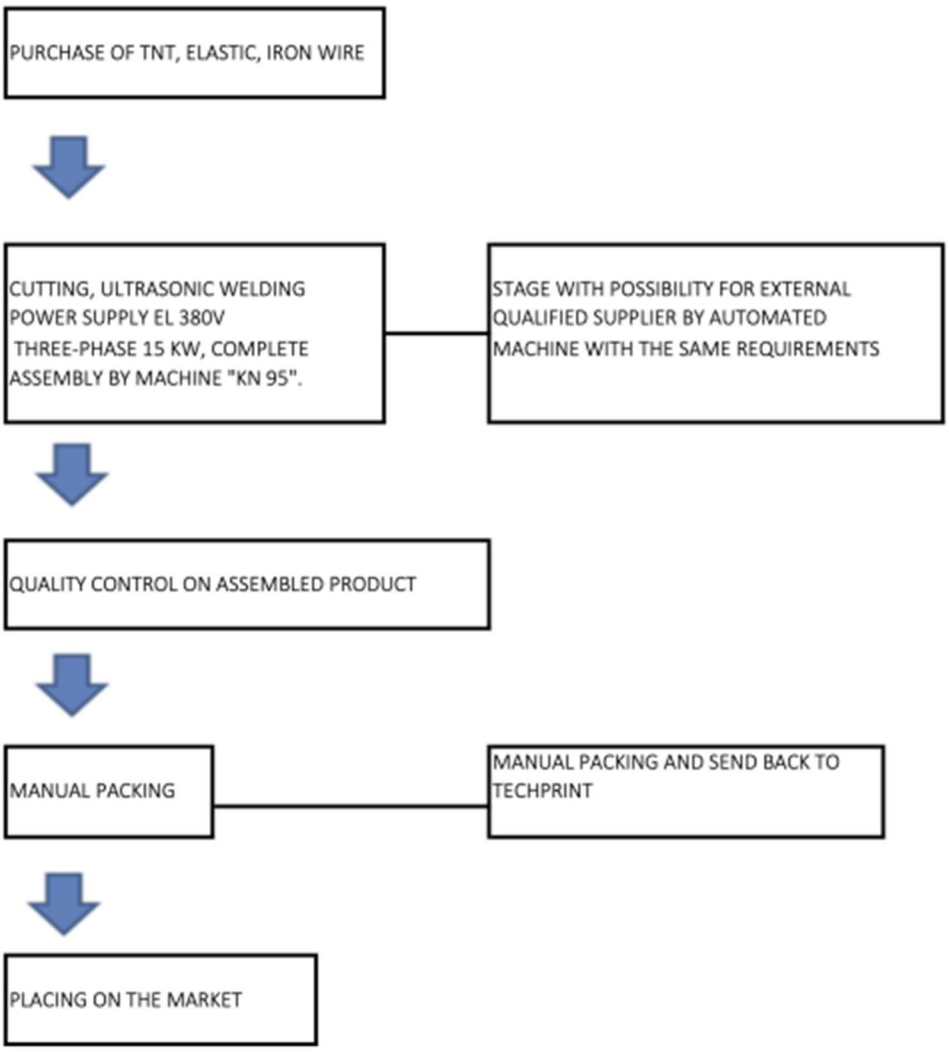
Tech Print

CICLO PRODUTTIVO



Le prove analitiche sono compiute a fine ciclo produttivo

PRODUCTION FLOW CHART



ANALYTICAL TESTS ARE CARRIED OUT AT THE END OF THE PRODUCTION CYCLE

1. CONTROLLO DEI PROCESSI

Di seguito la gestione dei processi con relative misure di controllo e monitoraggio.

Processo	Specifiche tecniche	Requisiti per il personale	Requisiti dell'attrezzatura	Parametro di controllo	Ulteriori metodi di verifica
Approvvigionamento di **- TNT POLYESTER 60 GR/MQ (Strato esterno)** **- MELTBLOWN 25 GR/MQ** **- TNT POLIPROPILENE 30 GR/MQ** **- MELTBLOWN 25 GR/MQ** **- TNT POLIPROPILENE 60 GR/MQ (Strato interno)** **Elastico** **Stringinaso**	Il materiale acquistato deve sempre essere il medesimo e corrispondente al materiale approvato (testato dal laboratorio di analisi).	/	Quelli indicati in fase di registrazione e qualifica del fornitore secondo la materia prima fornita	Procedura "approvvigionamento di beni e servizi" Procedura "monitoraggio misura e analisi del prodotto"	**Visiva sul prodotto acquistato e sulle schede tecniche di prodotto.** **Verifica mensile a campione sulla grammatura (corrispondenza del peso al metro quadro della materia prima in arrivo rispetto a quanto dichiarato)** **Compilazione mod 006 sui controlli quotidiani.**

Assemblaggio mascherine da parte di TECH PRINT	L'assemblaggio delle mascherine avviene in maniera totalmente automatica mediante apposita linea di produzione "kn95", ossia: Accoppiatura della stratificazione, alimentazione in continuo del ponticello nasale. In contemporanea vengono timbrati con marcatura CE. A mezzo di manipolazione elettro-pneumatica viene effettuata la saldatura ad ultrasuoni. La mascherina viene piegata verticalmente per conferire la conformazione finale. Vi è un ultimo modulo di saldatura finale che fissa la piega trasversale. Prima dell'uscita del prodotto viene effettuato il taglio del materiale in eccesso. La mascherina prodotta viene imbustata da operatore dedito al confezionamento o mediante apposita macchina imbustatrice..	Considerata la particolarità operativa in fase emergenziale "Covid-19" che esula dalle ordinarie procedure di produzione, consolidato che si deve lavorare con un doppio profilo di attenzione sia della popolazione in generale sia per i lavoratori impiegati nelle produzioni, al fine di minimizzare il rischio biologico si richiede l'utilizzo di guanti e mascherina protettiva. Inoltre si richiede la sanificazione delle mani ad ogni cambio turno o pause con efficace prodotto idroalcolico al 70% etanolo. Ulteriori informazioni si possono trovare sul PROTOCOLLO Tech Print.	Le attrezzature devono risultare pulite e sanificate e periodicamente monitorate anche dal punto di vista del funzionamento.	Vigilanza e controllo	**Controllo visivo della qualità sul prodotto finito.** **Analisi e test su prodotto finito e confezionato da parte di laboratorio certificato.** **Analisi periodiche ravvicinate non necessarie (v. PR 022)** **Compilazione Mod 006 giornaliero**

Below is the process management with related control and monitoring measures.

PROCESS	Technical specifications	Requirements for employees	Equipment requirements	Control parameter	Further verification methods
1. Supply of - TNT POLYESTER 60 GR/MQ (Outer layer) - MELTBLOWN 25 GR/MQ - TNT POLYPROPYLENE 30 GR/MQ - MELTBLOWN 25 GR/MQ Elastic Tightening	The purchased material must always be the same and correspond to the material approved (tested by the laboratory of analysis).		Those indicated during registration and qualification of the supplier according to the supplied raw material	Procedure "supply of goods and services" Procedure "Product measurement and analysis monitoring"	Visual check on the purchased product and on the product data sheets. Monthly sample verification on the weight (correspondence of the weight to the square meter of the raw material arriving compared to the declared one) Compilation mod 006 on daily checkings.

Mask assembly by TECH PRINT	The assembly of the masks takes place in a totally automatic way through a special production line "kn95", ie: Lamination coupling, continuous feeding of the bridge nasal. At the same time they are stamped with CE marking.Ultrasonic welding is carried out by means of electro-pneumatic manipulation.The mask is folded vertically to give the final shape There is a final welding module that fixes the cross fold. Before the product is released, the excess material is cut. The mask produced is bagged by an operator engaged in packaging or by special bagging machine..	Considered the operational peculiarity in the emergency phase "Covid-19" that goes beyond the ordinary production procedures, consolidated that you must work with a double profile of attention both of the population in general and for workers employed in production, in order to minimize the biological risk requires the use of gloves and protective mask It's also required the sanitization of the hands at each shift change or breaks with effective hydroalcoholic product 70% ethanol. More information can be found on Tech Print PROTOCOL	Equipment must be cleaned and sanitized and regularly monitored, including from the point of view of operation.	Monitoring and control	Visual quality control on the finished product.Analysis and testing on finished and packaged product by certified laboratory.No need for close periodic analyses (v. PR 022)Daily compilation of Mod 006

100% MADE IN ITALY

PROTECH

DICHIARAZIONE DI CONFORMITA' DEL PRODUTTORE

DECLARATION OF CONFORMITY EU NR.001

in according to EN 149:2001+A1:2009 e Reg EU 425/2016

CE

The manufacturer

Tech Print

TECHPRINT SRL UNIPERSONALE
Address : Via W. Tobagi, 7 - 59100 Prato (PO)
PEC address: techprintsrl@pec.it

Declares under its own responsibility that Personal Protective Equipment described here after

Name	**HALF-FACE RESPIRATOR - Foldable disposable respirator**
STANDARDS	EN 149:2001+A1:2009
CLASS	Personal Protective Equipment (PPE) category III
Model	PRO TECH FFP2 NR - LOT 0121 M501
Year of construction	2021

CE 2233

Conformity to type based on module B+C2 under surveillance of Notify Body Gep Teszt N.2233
Devices are compliant with:

STANDARDS	EN 149:2001+A1:2009

Prato, February 10th 2021

TECH PRINT S.r.l. Unipersonale
sede leg.: Via W. Tobagi, 39 PRATO
sede op.: Via delle Fonti, 354/6 PRATO
C.F. e P.I. 02302860974

Jianrui Cai
Chief Executive

100% MADE IN ITALY

PROTECH

CHIARIMENTI & SPIEGAZIONI

R: Nando

GL

Giuseppe Lorenzi <giuseppe.lorenzi@technoanalisys.com>
A Carla Techprint
Cc tuccini, elisa; Andrea Moretti; Jianrui

Rispondi | Rispondi a tutti | Inoltra | ...

martedì 23/03/2021 08:57

Buongiorno Carla,

NANDO (New Approach Notified and Designated Organizations) è una banca dati messa a disposizione dall'UE che raccoglie tutti i dati relativi agli organismi notificati europei. Un Organismo Notificato è un'organizzazione designata da un paese appartenente all'UE per valutare la conformità di determinati prodotti prima di essere immessi sul mercato. Questi organismi valutano la conformità in funzione della legislazione applicabile (norme) quando è richiesta una terza parte.
Ogni stato membro
Ogni paese europeo ha il proprio Ente Unico di accreditamento, che opera in linea con il **Regolamento CE 765/2008** e la norma internazionale ISO/IEC 17011.
Accredia è l'Ente designato dal governo italiano ad attestare la competenza, l'indipendenza e l'imparzialità degli organismi e dei laboratori che verificano la conformità dei beni e dei servizi alle norme.
NAH (National Accreditation Autority) è l'Ente designato dal governo ungherese ad attestare la competenza, l'indipendenza e l'imparzialità degli organismi e dei laboratori che verificano la conformità dei beni e dei servizi alle norme.

L'organismo Notificato Gep Teszt presso cui si è fatta la certificazione delle mascherine è un organismo accreditato ISO 17065 e ha il laboratorio accreditato ISO 17025.

Spero di essere stato chiaro

A disposizione per ulteriori informazioni e chiarimenti
Cordialmente
Giuseppe Lorenzi
Cell. +39 348 860 8256

TECHNO ANALISYS
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