

SCHEDA TECNICA



MADE
CONSULTING

Made in
Italy

SIRIA 20 Small FFP2 NR
nata per i visi più piccoli

CE 2233 EN 149:2001

Imbustate singolarmente

Marcate a laser o a ultrasuoni per evitare sostanze tossiche degli inchiostri

DESCRIZIONE

- La semimaschera filtrante antipolvere SIRIA 20 Small FFP2 NR prodotta dalla MADE CONSULTING SRL creata per i visi più piccoli come quelli dei bambini, offre un efficace protezione delle vie respiratorie da particelle solide e/o liquide non volatili (polveri, fumi, nebbie)
- Corpo filtrante di forma pieghevole
- Ferretto stringinaso in grado di assicurare un'ottima adattabilità ad ogni tipo di volto
- Comodi elastici per le orecchie LATEX FREE
- La marcatura NR indica che la semimaschera facciale è monouso, ovvero utilizzabile per non più di 8 ore di lavoro
- Prodotto testato in accordo alla normativa EN 149:2001+A1:2009 certificato da ente notificatore accreditato 2233
- Prodotto imbustato singolarmente per garantire igiene e perfetta conservazione ed evitare qualsiasi contaminazione

CONFEZIONAMENTO

- Busta contenente 1 pezzo

MATERIALI

- Corpo filtrante composto più strati di tessuto non tessuto di polipropilene
- Elastici latex free skin friendly
- Peso: 4,3 grammi

IMMAGAZZINAMENTO E TRASPORTO

- La semimaschera filtrante antipolvere SIRIA 20 Small FFP2 ha una durata di vita di 36 mesi
- La data di scadenza è indicata sulla confezione. Il prodotto deve essere conservato in un ambiente pulito ed asciutto dove la temperatura è tra 5° e 40°C e l'umidità relativa è inferiore all'80%. Per l'immagazzinamento ed il trasporto utilizzare la confezione originale.

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SIRIA 20 FFP2 NR

CE 2233 EN 149:2001

Imbustate singolarmente

Marcate a laser o a ultrasuoni per evitare sostanze tossiche degli inchiostri

DESCRIZIONE

- La semimaschera filtrante antipolvere SIRIA 20 FFP2 NR prodotta dalla MADE CONSULTING SRL offre un efficace protezione delle vie respiratorie da particelle solide e/o liquide non volatili (polveri, fumi, nebbie).
- Corpo filtrante di forma pieghevole
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CONFEZIONAMENTO

- Busta contenente 1 pezzo

MATERIALI

- Corpo filtrante composto più strati di tessuto non tessuto di polipropilene
- Elastici latex free skin friendly
- Peso: 4,3 grammi

IMMAGAZZINAMENTO E TRASPORTO

- La semimaschera filtrante antipolvere SIRIA 20 FFP2 ha una durata di vita di 36 mesi
- La data di scadenza è indicata sulla confezione. Il prodotto deve essere conservato in un ambiente pulito ed asciutto dove la temperatura è tra 5° e 40°C e l'umidità relativa è inferiore all'80%. Per l'immagazzinamento ed il trasporto utilizzare la confezione originale.

SCHEDA TECNICA



Made in
Italy

MADE
CONSULTING

SIRIA 20 Black FFP2 NR

CE 2233 EN 149:2001

Imbustate singolarmente

Marcate a laser o a ultrasuoni per evitare sostanze tossiche degli inchiostri

DESCRIZIONE

- La semimaschera filtrante antipolvere SIRIA 20 Black FFP2 NR prodotta dalla MADE CONSULTING SRL offre un efficace protezione delle vie respiratorie da particelle solide e/o liquide non volatili (polveri, fumi, nebbie).
- Corpo filtrante di forma pieghevole
- Ferretto stringinaso in grado di assicurare un ottima adattabilità ad ogni tipo di volto
- Comodi elastici per le orecchie LATEX FREE
- La marcatura NR indica che la semimaschera facciale è monouso, ovvero utilizzabile per non più di 8 ore di lavoro
- Prodotto testato in accordo alla normativa EN 149:2001+A1:2009 certificato da ente notificatore accreditato 2233
- Prodotto imbustato singolarmente per garantire igiene e perfetta conservazione ed evitare qualsiasi contaminazione

CONFEZIONAMENTO

- Busta contenente 1 pezzo

MATERIALI

- Corpo filtrante composto più strati di tessuto non tessuto di polipropilene
- Elastici latex free skin frendly
- Peso: 4,3 grammi

IMMAGAZZINAMENTO E TRASPORTO

- La semimaschera filtrante antipolvere SIRIA 20 Black FFP2 ha una durata di vita di 36 mesi
- La data di scadenza è indicata sulla confezione. Il prodotto deve essere conservato in un ambiente pulito ed asciutto dove la temperatura è tra 5° e 40°C e l'umidità relativa è inferiore all'80% . Per l'immagazzinamento ed il trasporto utilizzare la confezione originale.



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/GT130/166/2010/E/2233

Record of examination No.: VD35/130/2010/E/2233 and VD36/130/X1/2020/EN

The EU type-examination certificate is not transferable.

1. Product designation: **Particle filtering half mask**
SIRIA 20 FFP2 non reusable particle filtering half mask without valves in white colour.
SIRIA 20 Black FFP2 non reusable particle filtering half mask without valves in black colour.
SIRIA 20 Small FFP2 non reusable particle filtering half mask without valves. in white colour and smaller size.
 Serial / Model No.: SIRIA 20, SIRIA 20 Black, SIRIA 20 Small
 Year of production: 2020
2. Name and address of the holder of the certificate (Manufacturer or authorized representative):
MADE CONSULTING SRL
 Address: 13 Via Nicola Fele 8, Qualiano (NA) 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
5. Identification data of the records of examination for compliance of PPE:
 - a. Certification Body: GÉPTESZT Kft.
 Record of examination: VD35/130/2010/E/2233 and VD36/130/X1/2020/EN
 - 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
 Annexes:
 - Users information
 - Technical file
7. 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.

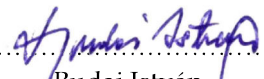
Legal remedy can be applied against the condition stated in the EU type-examination Certificate. The application for appeal should be submitted to the Director Manager of GÉPTESZT Kft., and the application will be judged by the board of GÉPTESZT Kft. Certificate Body.

The type tested complies with the regulation (EU) 2016/425 of the European Parliament of the Council.

The present certificate is valid until 19th October, 2025

Budapest, 11th December, 2020- HUNGARY

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



 Budai István
 Head of Certification Body

MASCHERA DI PROTEZIONE MASK DEFENDER

SIRIA 20 FFP2 NR
IMBUSTATE SINGOLARMENTE



IT AVVERTENZE

1) Questo facciale filtrante non protegge da contaminanti in fase gas o vapore; 2) Non usare in ambiente con insufficiente contenuto di ossigeno (<17%); 3) Non utilizzare quando le concentrazioni del contaminante sono pericolose per la salute o dove la natura e la concentrazione del contaminante sono sconosciute; 4) Non utilizzare per la fuga; 5) Non modificare o alterare in alcun modo il respiratore; 6) Il facciale filtrante va sostituito se è danneggiato o se la resistenza respiratoria 7) Si sconsiglia l'uso in presenza di barba o basette lunghe che non permettono il contatto diretto tra il volto e i bordi del respiratore; 8) L'utilizzatore deve essere addestrato al corretto utilizzo del dispositivo prima dell'impiego; 9) Per l'impiego in ambienti con il rischio di esplosione bisogna rispettare le norme relative 10) Devono essere correttamente conservati, nella loro confezione integra in ambienti asciutti e non contaminati (temperatura da +5 °C a +40°C - Umidità relativa <60%).

EN WEARING

1) This filtering face piece does not protect against gas or vapor phase; 2) Do not use in an environment with insufficient oxygen content (<17%); 3) Do not use when the concentrations of the contaminant are dangerous for healths or where the nature and concentration of the contaminant are unknown; 4) Do not use for escape; 5) Do not modify or alter the respirator in any way; 6) The filtering face piece must be replaced if it is damaged or if the respiratory resistance becomes excessive; 7) It is not recommended for use with a beard grip or longsideburns that do not allow direct contact between the face and the edges of the respirator; 8) The user must be trained in the correct use of the device before use; 9) For use in environments with risk of respirator the relative standards must be respected; 10) it must be properly stored, with packaging intact in dry and uncontaminated environments (temperature from +5 °C to +40 °C - relative humidity <60).

ISTRUZIONI PER L'INDOSSAMENTO

- 1) Aprire la mascherina, e tirare gli elastici per controllare che tutto sia apposto
- 2) Indossare la mascherina appoggiandola prima sul naso
- 3) Agganciare gli elastici dietro le orecchie
- 4) Conformare lo stringinaso facendolo aderire ai contorni
- 5) Premere leggermente per ottenere la migliore aderenza possibile anche sulle guance e sotto il mento.

WEARING INSTRUCTION

- 1) Open the mask, and pull the elastics bands to check that everything is ok
- 2) Wear the mask by placing it first on the nose;
- 3) Hook the elastic bands behind the ears
- 4) Adjust the nose clip making it stick to the contours;
- 5) Press lightly to obtain the best possible suction on the cheeks and under the chin.



ISTRUZIONI PER L'USO - DESCRIZIONE

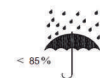
Le semimaschere filtranti FFP2 NR SIRIA 20 della MADE CONSULTING SRL sono conformi agli standard della norma EN 149:2001+A1:2009. Utilizzare le avvertenze appropriate controllando a quale categoria appartiene il facciale - l'indicazione si trova sulla scatola e sul facciale stesso. E' responsabilità dell'utilizzatore assicurarsi che il facciale filtrante fornisca l'adeguato livello di protezione contro il tipo e la concentrazione di contaminanti presenti nell'ambiente dove deve essere utilizzato. Le semimaschere filtranti FFP2 NR SIRIA 20 MADE CONSULTING SRL possono essere utilizzate per proteggere gli utilizzatori da aerosol solidi e liquidi non volatili. La certificazione CE assicura che queste semimaschere filtranti (in quanto dispositivo di III Categoria) soddisfino i requisiti essenziali di salute e sicurezza previsti dal Regolamento Europeo 16/425/UE ed il numero 2233 identifica l'organismo notificato (Gépteszt Kft. Gyenes utca 12., 1032 Budapest, Hungary) responsabile della certificazione e del controllo in accordo al modulo C2 del regolamento europeo 16/425/UE.

Le dichiarazioni di conformità sono disponibili sul sito: www.dpi-industry.com

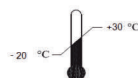
EN INSTRUCTIONS FOR USE - DESCRIPTION

The half face masks FFP2 NR SIRIA 20 product to MADE CONSULTING SRL are compliant with the standards of EN 149:2001+A1:2009 (the specific classes FFP1, FFP2, FFP3). Use the appropriate warnings by checking which category belongs to the face mask-the indication is on the box and on the face mask itself. It is the responsibility of the user used that the facial filter provides the adequate level of protection against the type and concentration of contaminants present in the environment and where it must be used. MADE CONSULTING SRL Half-masks FFP2 NR SIRIA 20 can be used to protect users from solid and non-volatile liquid aerosols. The CE certification provided by these filter half masks (as a Category III device) meet the essential requirements of greeting and safety provided for by the European Regulation 16/425/UE and the number 2233 identifies the notified agent (Gépteszt Kft. Gyenes utca 12., 1032 Budapest, Hungary) responsible for certification and control in accordance with module C2 of the European regulation 16/425/UE.

The declarations on conformity are available on the website: www.dpi-industry.com



Do not exceed % of relative humidity (RH) during storage indicate in the pictogram



Store within the temperatures indicated in the pictogram



Read the expiry date Quoted as 09/2023



Read the information notice carefully

Prodotto da:

MADE CONSULTING SRL,
San Marco dei Cavoti 82029 (BN) - Italy
Cel +39 3791401958
WWW.DPI-INDUSTRY.COM
dpi.evolution.industry@gmail.com

CE 2233



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: MADE CONSULTING SRL
Address: Via Nicola Fele 8, Qualiano (NA) ITALY

Model: SIRIA 20

Classification: FFP2

Exhalation valve: no

Inhalation valve: no

Uses: non reusable

Project number: GT130

Test report number: VD35/130/2010/E/2233

Project worksheet number: VD-34-2020-130

Date of the test: 2020.10.06-2020.10.17.

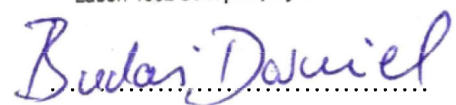
Samples received date: 2020.10.06.

Sample numbers: 130-1 - 130-45

Attachment: no

Issued: Budapest, 2020.10.17.

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

A handwritten signature in blue ink that reads "Budai Dániel". The signature is written in a cursive style and is positioned above a dotted horizontal line.

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 mask consist of 4 layers: between 2 superbound layers there are 2 meltblown layers. The mask has 2 earloops. To shape at the nose is possible with metal wire coated in polyester.





Short description of EU-type tests:

Requirement	Test method	Description	Passed/Failed/NA
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)	Passed
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	Passed

Analysis and details of EU-type test results:

7.4 Packaging

Each mask is packed in a transparent plastic bag. It gives enough protection against mechanical damage or contamination.

PASSED

7.5 Material

- conditioning S.W.: Sample nr: 130-25 to 130-27
None of the particle filtering half masks have suffered mechanical failure of the facepiece or straps.
- conditioning T.C.: Sample nr.: 130-8 to 130-10
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 $(1,3 \pm 0,2)$ m for 5 min;
 - crawling on the level with headroom of $(0,70 \pm 0,05)$ m for 5 min;
 - filling a small basket 20x in 10 min;

Subjects	Samples	Conditioning	Result
BA	130-1	A.R.	PASSED
LA	130-2	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
BA	140	155	105	65
BD	120	130	135	55
BI	140	120	110	65
KCS	113	143	127	54
BP	120	125	116	57
LA	123	140	105	60
NA	130	120	130	50
NT	122	134	142	57
RE	115	138	112	48
TL	115	130	110	53

Subject	Sample	Cond.	Total inward leakage, %					Mean, %
			Walk	Head left/right	Head up/down	Talk	Walk	
BA	130-3	A.R.	3,02	4,16	3,09	3,66	3,57	3,50
BD	130-4	A.R.	7,60	6,67	6,66	11,62	6,29	7,77
BI	130-5	A.R.	5,37	5,55	4,83	5,40	3,76	4,98
KCS	130-6	A.R.	4,08	6,74	6,62	5,16	4,29	5,38
BP	130-7	A.R.	3,58	3,74	3,36	3,77	2,84	3,46
LA	130-8	T.C.	1,38	2,25	2,43	3,74	1,86	2,33
NA*	130-9	T.C.	6,66	5,55	5,53	8,54	6,02	6,46
NT	130-10	T.C.	2,82	6,28	5,09	5,11	3,74	4,61
RE*	130-11	T.C.	1,55	2,97	2,13	3,77	1,86	2,46
TL	130-12	T.C.	3,79	4,94	5,25	6,16	4,11	4,85

49 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%.

*the subject had to wear a fastening element (which was not in the package) so that the mask could fit more tightly. The mask may not fit suitable (too loose) for some users, so we advise to give a fastening elements for each mask, and warning in the user instruction.

PASSED

7.9.2 Penetration of filter material: NaCl

NaCl aerosol: concentration: 4-12 mg/m³, flow: 95 l/min

Sample	Conditioning	Penetration, %	Exposure, %
130-13	A.R.	0,40	NA
130-14	A.R.	0,76	NA
130-15	A.R.	0,75	NA
130-16	S.W.	0,51	NA
130-17	S.W.	0,49	NA
130-18	S.W.	0,48	NA
130-19	M.S→T.C.	NA	2,14
130-20	M.S→T.C.	NA	2,09
130-21	M.S→T.C.	NA	2,29
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/m³, flow: 95 l/min

Sample	Conditioning	Penetration, %	Exposure, %
130-22	A.R.	3,16	NA
130-23	A.R.	3,27	NA
130-24	A.R.	3,34	NA
130-25	S.W.	3,49	NA
130-26	S.W.	3,61	NA
130-27	S.W.	3,51	NA
130-28	M.S→T.C.	NA	4,59
130-29	M.S→T.C.	NA	5,37
130-30	M.S→T.C.	NA	5,57
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
130-30	T.C.
130-28	T.C.
130-23	A.R.
130-22	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%
130-43	0,61
130-44	0,60
130-45	0,57

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
130-1
130-2

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 resistance 160 l/min				
		30 l/min	95 l/min	ahead	vert. upwards	vert. downwards	left	right
130-34	A.R.	0,55	1,68	2,18	2,15	2,17	2,18	2,19
130-35	A.R.	0,49	1,61	2,14	2,14	2,14	2,13	2,13
130-36	A.R.	0,56	1,66	2,14	2,13	2,14	2,13	2,13
130-37	T.C	0,45	1,31	2,07	2,02	2,06	2,06	2,05
130-38	T.C	0,44	1,34	1,90	1,89	1,90	1,89	1,90
130-39	T.C	0,44	1,30	1,94	1,93	1,94	1,93	1,94
130-40	S.W.	0,53	1,63	2,28	2,28	2,29	2,29	2,28
130-41	S.W.	0,55	1,66	2,39	2,37	2,38	2,39	2,37
130-42	S.W.	0,52	1,54	2,25	2,25	2,24	2,25	2,24
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

Result of EU type test:

The above described **SIRIA 20 particle filtering half mask** at the time of the test is **conformed** to the relevant test requirements of EN 149:2001+A1:2009 class FFP2.



SZERZŐDÉS CONTRACT

C2 MODUL SZERZŐDÉS EGYÉNI VÉDŐESZKÖZ TÍPUSMEGFELELŐSÉGÉNEK ELLENŐRZÉSÉRE

C2 MODULE CONTRACT FOR ASSESSMENT TO CONFORMITY TO TYPE OF PERSONAL PROTECTION EQUIPMENT

ÉRVÉNYES VISSZAVONÁSIG VALID UNTIL RECALLED

amely létrejött egyrészről **MADE CONSULTING SRL** Megrendelő másrészről a **GÉPTESZT Kft.*** Ellenőrző Szervezet (1037 Budapest, Jablonka út. 79. a továbbiakban: Kijelölt Szervezet) között az alábbi feltételek mellett.
*A Gépteszt Kft.-t légzésvédő eszközök megfelelőségértékelési tevékenységére vonatkozóan a Magyar Állam 2020. június 11-én bejelentette az Európa Unióhoz, a végleges regisztráció ezt követően két hónappal, 2020. augusztus 11-én történik meg.

*concluded between **MADE CONSULTING SRL** on the one part, hereinafter referred to as the Purchaser and **GÉPTESZT Ltd.*** as Inspection Body (1037 Budapest, Jablonka St. 79., hereinafter referred to as Notified Body) under the following terms and conditions.*

**Gépteszt Ltd. was notified to the European Union by the Hungarian State on 11th of June 2020 regarding the conformity assessment activities of respiratory protective equipmen, the final registration will take place two months later, on 11th of August, 2020.*

1. A szerződés tárgya

Megfelelőség ellenőrzése a 2016/425 EU rendelet 19. cikk c.) i. pontjában valamint a VII. mellékletében foglaltaknak megfelelő a belső gyártásellenőrzésen és a véletlenszerű időközönként, felügyelet mellett végzett termékellenőrzésen alapuló típusmegfelelőség ellenőrzése (C2 modul) a Gyártó telephelyén (C/DA PERRERI, SAN MARCO DEI CAVOTI 82029 (BN), ITALY)

1. Scope of contract

Compliance inspection with regulation 2016/425 (EU) Article 19 (c.) (i) point and also in accordance with annex VII. in order to control conformity to type based on internal production control plus supervised product checks at random intervals (module C2) at the Manufacturer's site: (C/DA PERRERI, SAN MARCO DEI CAVOTI 82029 (BN), ITALY)

2. A szerződő felek kötelezettségei:

2.1. Az Ellenőrző Szervezet kötelezettségei

- 2.1.1. Az Ellenőrző Szervezet az ellenőrzést lefolytatja, amelynek alapját a benyújtott védőeszköz és a vonatkozó dokumentációk, továbbá a már rendelkezésre álló vizsgálati eredmények képezik.
- 2.1.2. Az Ellenőrző Szervezet a helyszínen gyártói auditot végez.
- 2.1.3. Az Ellenőrző Szervezet a védőeszköz, illetve a vonatkozó gyártási és végtermék ellenőrzési rendszer megfelelőségére vonatkozó megállapításokról jegyzőkönyvet és tanúsítványt, továbbá bármilyen nemmegfelelés esetén hibajegyzéket állít ki.
- 2.1.4. Ha az Ellenőrző Szervezet az ellenőrzés alkalmával nemmegfelelőséget állapít meg, értesíti a Gyártót, megjelölve a hibajavító tevékenység határidejét.
- 2.1.5. Az Ellenőrző Szervezet az EU-típusvizsgálati tanúsítvány kiadásától számított 1 éven belül, később évente legalább egy alkalommal ellenőrzi a tanúsított védőeszközt, annak gyártási rendszerét, termékellenőrző vizsgálat céljából a gyártásból szükség szerint mintapéldányt vesz.



- 2.1.6. Az Ellenőrző Szervezet a Gyártót előzetesen tájékoztatja az ellenőrzés időpontjáról és tárgyáról.
- 2.1.7. Az Ellenőrző Szervezet az ellenőrzéseket 20 munkanapon belül teljeskörűen lefolytatja.
- 2.1.8. Az Ellenőrző Szervezet az ellenőrzési tevékenység végzése során tudomására jutott, a védőeszközre vagy a gyártóra vonatkozó információkat, adatokat a polgári jogi felelősség keretében bizalmasan kezeli, azokat harmadik személy részére nem szolgáltatja ki.

2.1. *Liabilities of Inspection Body*

- 2.1.1. *The Inspection Body performs the inspection based on the personal protective equipment and related documents submitted as well as the available results of the earlier inspections.*
- 2.1.2. *Inspection Body carries out a manufacturer's audit on site.*
- 2.1.3. *Inspection Body shall issue test reports of the results of the inspection regarding the compliance of the controlling system of the relevant manufacturing product and the end product. In case of non-compliance, Inspection Body shall make out a list of irregularities.*
- 2.1.4. *In case of revealing non-compliance during inspection, Inspection Body shall inform Manufacturer, fixing a deadline for correction.*
- 2.1.5. *Inspection Body shall inspect the certified personal protective equipment within 1 year from issuing the EU-type certificate, later at least once a year including the product, the manufacturing system and take a sample from production or storage for product check*
- 2.1.6. *Inspection Body informs Manufacturer about the date and subject of on-site assessment.*
- 2.1.7. *Inspection Body shall complete inspections within 20 working days.*
- 2.1.8. *Any information or data, received during the inspection by Inspection Body, about the personal protective equipment or Manufacturer, shall be regarded as confidential and shall not be shared with any third party.*

2.2. **A Gyártó kötelezettségei**

- 2.2.1. A Gyártó a tárgyban szereplő ellenőrzési tevékenység elvégzése érdekében együttműködik az Ellenőrző Szervezettel.
 - 2.2.2. A Gyártó vállalja, hogy a tanúsított védőeszköz ellenőrzésekhez szükséges dokumentációkat és mintapéldányokat biztosítja és annak gyártói auditra és termékellenőrző vizsgálatára vonatkozó költségét az ellenőrzést megelőzően kiegyenlíti.
 - 2.2.3. A Gyártó a tárgyban szereplő ellenőrzési tevékenység elvégzése érdekében vállalja a szükséges dokumentumok és termékek benyújtását a következők szerint:
 - Védőeszköz gyártásból származó típusonkénti mintapéldánya
 - A védőeszköz hiteles mintapéldánya
 - A védőeszköz gyártójának megnevezése
 - A védőeszköz származási helyének megnevezése
 - Tájékoztató/felhasználói információ magyar és/vagy angol nyelven
 - Tanúsító szerv által kiállított EU-típusvizsgálati tanúsítvány a védőeszközzel
 - CE-jelölés tartalma
 - EU-megfelelőségi nyilatkozat tervezete
 - Teljes körű műszaki dokumentáció
 - 2.2.4. A Gyártó hozzájárul, hogy az Ellenőrző Szervezet a vizsgálatok elvégzésére a GÉPTESZT Kft. EVE Vizsgálólaboratóriumát bevonja.
 - 2.2.5. **A Gyártó haladéktalanul tájékoztatja az Ellenőrző Szervezetet a gyártással kapcsolatos minden változásról és módosításról.**
 - 2.2.6. A Gyártó vállalja, hogy a szerződés tárgyát képező érkező panaszokról nyilvántartást vezet, és azt az ellenőrzések alkalmával bemutatja.
 - 2.2.7. A gyártó helyszínén begyűjtött minták szállításának költsége a Gyártót terheli
- 2.2.1. *Manufacturer shall cooperate with Inspection Body in the scope of the aforesaid actions.*
 - 2.2.2. *Manufacturer agrees to provide the relevant documentation and samples for the inspection of the certified personal protective equipment and settle the costs of the manufacturer's audit and product checks prior to the assessment.*
 - 2.2.3. *Manufacturer shall submit the following documents and products in the scope of the aforesaid inspections:*
 - *Sample from the production of the personal protective equipment (one of each type)*
 - *An authentic sample of the personal protective equipment (sealed sample)*
 - *Name of the manufacturer of the personal protective equipment*



- *Place of origin of the personal protective equipment*
- *Information booklet/User's guide in English*
- *EU-type certificate of the personal protective equipment issued by the certifying organization*
- *Content of EC mark*
- *Draft of the EU Declaration of Conformity*
- *Complete technical documentation*

2.2.4. *Manufacturer accepts the PPE Inspection Laboratory of GÉPTESZT Ltd. for the inspection tests.*

2.2.5. ***Manufacturer informs Inspection Body without delay about any modifications or changes regarding the manufacturing process.***

2.2.6. *Manufacturer agrees to record all complaints regarding the subject of the Contract and presents them at the time of inspections.*

2.2.7. *Manufacturer bears the shipping cost of the samples.*

3. A szerződés díja, fizetési feltételek, megszűnés

3.1. Az ellenőrzési tevékenység végzésének díja a gyártói audit és az elvégzett termékellenőrző vizsgálatok és a C2 jelentés díjából tevődik össze.

- helyszíni audit
- utazási költség
- darabvizsgálat ára
- C2 modul éves felügyeleti jelentés

3.2. Az ellenőrzési tevékenység elvégzéséhez az Ellenőrző Szervezet minden évben kalkulációt ad a tényleges termékszám alapján a Szolgáltatás közvetítőjének. A kalkuláció visszaigazolása után az Ellenőrző Szervezet kiállítja a számlát a Szolgáltatás közvetítőjének, majd elvégzi a szerződésben foglaltakat.

3.3. Fizetés módja: Az Ellenőrző Szervezet számlája alapján átutalással 30 napon belüli határidővel az IBAN: HU18 1176 3031 2026 7887 0000 0000 számlaszámra SWIFT: OTPVHUB

3.4. Jelen szerződés visszavonásig érvényes. Azonban a felek jogosultak írásban 6 hónappal az új C2 jelentés kiadása előtt felmondani.

3. Contract fee, payment terms, termination

3.1 *The fee of control assessment consists of the on-site assessment, product checks' price and Module C2 Annual Surveillance Report.*

- on-site assessment*
- travelling cost*
- product checks' price*
- Module C2 Annual Surveillance Report*

3.2 *The Inspection Body gives a calculation based on the actual product number for the Manufacturer. After confirmation of the calculation the Inspection Body issues the invoice for the Manufacturer, and performs the contract.*

3.3 *Payment method: Transfer to the bank account of the Inspection Body in 30 days: IBAN: HU18 1176 3031 2026 7887 0000 0000 bank account. SWIFT: OTPVHUB*

3.4 *Present contract valid until recall. However, the Parties have the right to terminate it in writing 6 months before the release of the new C2 Annual Surveillance Report.*

4. Egyéb rendelkezések

4.1. A Gyártó tudomásul veszi, hogy az Ellenőrző Szervezet az illetékes tanúsító szervnél eljár a kiadott EU-típusvizsgálati tanúsítvány (vagy EK-típustanúsítvány) felfüggesztése, visszavonása vagy egyéb intézkedés megtétele érdekében a következők szerinti esetekben:

- 4.1.1. a Gyártó az EU-típusvizsgálati tanúsítványt (vagy EK-típustanúsítványt) jogtalanul használja,
- 4.1.2. a Gyártó a gyártási folyamatát érintő változásról, módosításáról az Ellenőrző Szervezetet nem tájékoztatja,
- 4.1.3. az Ellenőrző Szervezet megállapítja, hogy a védőeszköz már nem elégíti ki a hiteles mintapéldányra vonatkozó követelményeket,
- 4.1.4. a Gyártó nem teszi lehetővé az ellenőrzést,



- 4.1.5. a Gyártó az ellenőrzés alkalmával észlelt nemmegfelelőséget a megadott határidőn belül nem szünteti meg.
- 4.2. A szerződés teljesítésekor az Ellenőrző Szervezet írásbeli értesítést küld a Gyártónak az Ellenőrző Szervezet hibáján kívüli okokból bekövetkező, vagy a Gyártó írásos kérelme alapján végzett többletszolgáltatás miatti határidő illetőleg díj változásról.
- 4.3. Ha a Gyártó nem fogadja el az Ellenőrző Szervezet szerződésmódosításra tett ajánlatát, az Ellenőrző Szervezet az addig felmerülő ráfordításokat kiszámlázza.
- 4.4. A Gyártó tudomásul veszi, hogy az ellenőrzési tevékenység alapját képező védőeszköz vizsgálatok során a mintapéldány roncsolódhat, meghibásodhat, ami a vizsgálatok jellegéből fakad és az ebből eredő kárért az Ellenőrző Szervezet nem felelős.
- 4.5. Az Ellenőrző Szervezet a szerződés teljesítését követően a mintapéldányt megsemmisíti.
- 4.6. Egyéb kérdésekben a PTK megbízási szerződésekre vonatkozó paragrafusai és a szerződés mellékletét képező „Az ellenőrzési eljárás ismertetése” című tájékoztató az irányadók

4. Miscellaneous

- 4.1. *Manufacturer accepts that Inspection Body shall take measures for the certifying organization, such as the suspension or the withdrawal of the EU type-examination certificate (or EC type-examination certificate) or taking any other action in the following cases:*
- 4.1.1. *Manufacturer illegally uses the EU type-examination certificate (or EC type-examination certificate),*
- 4.1.2. *Manufacturer does not inform Inspection Body about the change, modification of the production process,*
- 4.1.3. *Inspection Body establishes that the personal protective equipment no longer meets the requirements of the standard sample device,*
- 4.1.4. *Manufacturer does not allow inspection,*
- 4.1.5. *The incompliance revealed during inspection is not terminated until the given deadline.*
- 4.2. *Upon accomplishing the contract Inspection Body shall inform Manufacturer in writing about any changes in deadlines or fees due to extra services requested in writing by Manufacturer.*
- 4.3. *If Manufacturer does not accept the quotation of Inspection Body for the modification of the Contract, Inspection Body shall make out an invoice of all costs that have arisen until that date.*
- 4.4. *Manufacturer shall accept that the sample protective product may be damaged, destroyed during the inspection, due to the nature of tests and Inspection Body shall not be made responsible for that.*
- 4.5. *Inspection Body destroys the sample after completion of the service.*
- 4.6. *Any dispute shall be settled in accordance with the relevant section of the Civil Code of Hungary regarding contract and the Annex of the Contract called 'Controlling Procedure'.*

Dátum, Date: 2020.07.24.

Soriano Marcella
contact
Gyártó/Manufacturer

GÉPTESZT
Termelő eszközöket Felülvizsgáló és
Karbantartó Kft.
1037 Budapest, III. Jablonka u. 79.

Budai István
igazgató / director
GÉPTESZT Kft. (Ltd.)



PERSONAL PROTECTIVE EQUIPMENT PRODUCT CHECK ROUTINE TEST REPORT *for certificate extension*

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: MADE CONSULTING SRL
Address: Via Nicola Fele 8, Qualiano (NA) ITALY

Model: SIRIA 20 Black, SIRIA 20 Small

Classification: FFP2 NR

Exhalation valve: no

Inhalation valve: no

Uses: non reusable (NR)

Project number: GT130

Test report number: VD36/130/X1/2020/EN

Project worksheet number: VD-34-2020-130-X1

Date of the test: 2020.11.18-12.11.

Samples received date: 2020.11.09 and 2020.12.08.

Sample numbers: 1 - 13

Attachment: no

Issued: Budapest, 2020.12.11.

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

A handwritten signature in blue ink, appearing to read "Budai Dániel", is written over a dotted line.

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 added versions:

- **SIRIA 20 Black:** as same construction as the certified one, but the outer layer is black
- **SIRIA 20 Small:** as same construction as the certified one, but smaller size

Original version description in VD35/130/2010/E/2233





Short description of routine tests:

Requirement	Test method	Description	Result
7.9.1	8.5	Total inward leakage	Passed
7.9.2	8.11	Penetration of filter material: paraffin oil	Passed
7.10	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
7.16	8.9	Breathing resistance	Passed

Analysis and details of routine test results:

SIRIA 20 Small

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
NT	122	134	142	57
SA	100	120	120	50
NA	130	120	130	50

Subject	Sample	Cond.	Total inward leakage, %					Mean, %
			Walk	Head left/right	Head up/down	Talk	Walk	
NT	4	A.R.	2,73	3,45	4,27	4,18	2,37	3,40
SA	5	A.R.	2,88	4,32	4,76	7,97	4,89	4,96
NA	6	A.R.	4,31	4,89	3,91	5,77	4,56	4,69

30 out of the 30 individual exercise results for total inward leakage were not greater than 11 % and 3 out of the 3 individual wearer arithmetic means for the total inward leakage were not greater than 8%.

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%
7	051

The carbon dioxide content of the inhalation air (dead space) did not exceed an average of 1,0 V/V %.

PASSED



7.16 Breathing resistance

Sample	Conditioning	Inhalation resistance		Exhalation resistance 160 l/min				
		30 l/min	95 l/min	ahead	vert. upwards	vert. downwards	left	right
1	A.R.	0,46	1,76	2,83	2,83	2,83	2,82	2,82
2	A.R.	0,47	1,73	2,81	2,82	2,81	2,81	2,82
3	A.R.	0,50	1,74	2,77	2,78	2,76	2,77	2,76
Maximum permitted		0,7	2,4	3,0				

None of the measured values exceeded the maximum values.

PASSED

SIRIA 20 Black

7.9.2 Penetration of filter material: paraffin oil

Paraffin aerosol: concentration: 15-25 mg/m³, flow: 95 l/min

Sample	Conditioning	Penetration, %	Exposure, %
8	A.R.	2,01	NA
9	A.R.	1,88	NA
10	A.R.	1,95	NA
Maximum permitted:		6 %	

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

PASSED

7.11 Flammability

Sample	Conditioning
11	A.R.

The materials used do not present a danger for the wearer and are not of highly flammable nature. The sample did not burn.

PASSED

7.16 Breathing resistance

Sample	Conditioning	Inhalation resistance		Exhalation resistance 160 l/min				
		30 l/min	95 l/min	ahead	vert. upwards	vert. downwards	left	right
12	A.R.	0,66	2,02	2,73	2,72	2,71	2,72	2,72
13	A.R.	0,67	1,99	2,71	2,70	2,68	2,68	2,68
Maximum permitted		0,7	2,4	3,0				

None of the measured values exceeded the maximum values.

PASSED

Result of the routine test: PASSED

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

EU DECLARATION OF CONFORMITY

We,

MADE CONSULTING SRL, Via Nicola Fele 8, QUALIANO (NA).

declare under our sole responsibility, that the product below:

Description of the Product : FFP2 NR

Model Name : SIRIA 20, Siria 20 Black, Siria 20 Small

meets the following European regulation(s):
2016/425 (EU) Regulations.

Applicable harmonised standard: EU 149:2001+ A1:2009

the notified body **GEPTESZT KFT. (No. 2233)**
1037 Budapest, Jablonka u. 79.
Hungary

performed the EU type-examination (Module B) and issued the EU type-examination certificate.

No.: TD11/GT130/166/2010/X1/E/2233

the PPE is subject to the conformity assessment procedure *conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)* under surveillance of the notified body **GEPTESZT KFT. (No. 2233)**

MADE CONSULTING SRL,
VIA NICOLA FELE 8, 80019 QUALIANO (NA)
P.IVA 09206661218

MARCELLA SORIANO, MADE CONSULTING SRL
Qualiano 11/12/2020

MANAGING DIRECTOR
MARCELLA SORIANO



EU DECLARATION OF CONFORMITY

We,

MADE CONSULTING SRL, Via Nicola Fele 8, QUALIANO (NA).

declare under our sole responsibility, that the product below:

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meets the following European regulation(s):
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the notified body **GEP TESZT KFT. (No. 2233)**
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MADE CONSULTING SRL,
VIA NICOLA FELE 8, 80019 QUALIANO (NA)
P.IVA 09206661218

MARCELLA SORIANO, MADE CONSULTING SRL
Qualiano 11/12/2020

MANAGING DIRECTOR
MARCELLA SORIANO





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/GT130/166/2010/E/2233

Record of examination No.: VD35/130/2010/E/2233 and VD36/130/X1/2020/EN

The EU type-examination certificate is not transferable.

1. Product designation: **Particle filtering half mask**
SIRIA 20 FFP2 non reusable particle filtering half mask without valves in white colour.
SIRIA 20 Black FFP2 non reusable particle filtering half mask without valves in black colour.
SIRIA 20 Small FFP2 non reusable particle filtering half mask without valves. in white colour and smaller size.
 Serial / Model No.: SIRIA 20, SIRIA 20 Black, SIRIA 20 Small
 Year of production: 2020
2. Name and address of the holder of the certificate (Manufacturer or authorized representative):
MADE CONSULTING SRL
 Address: 13 Via Nicola Fele 8, Qualiano (NA) 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
5. Identification data of the records of examination for compliance of PPE:
 - a. Certification Body: GÉPTESZT Kft.
 Record of examination: VD35/130/2010/E/2233 and VD36/130/X1/2020/EN
 - 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
 Annexes:
 - Users information
 - Technical file
7. 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.

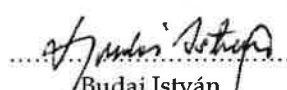
The EU type-examination certificate will be withdrawn in case of existence of conditions stated in Article 32 point 5. and in Annex V. 7.7. of regulation (EU) 2016/425 of the European Parliament of the Council.

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 19th October, 2025

Budapest, 11th December, 2020- HUNGARY

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

 Budai István
 Head of Certification Body

2021-02-10 11:22



Notified Body registered in the EU – number 2233

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Certificate checker

In case you cannot find a certain certificate, please write an email to
nb2233@gepteszt.hu.

Certificate number:

Or

Manufacturer:

MADE CONSULTING

and model:

SIRIA 20

Search

Results:

Certification number: TD11/GT130/166/2010/E/2233

Manufacturer/Holder: Made Consulting SRL

Model: SIRIA 20

Description: particle filtering half mask

Standard/scope: EN:149:2001+A1:2009

Date of issue: 2020-10-19

Expiry date: 2025-10-19