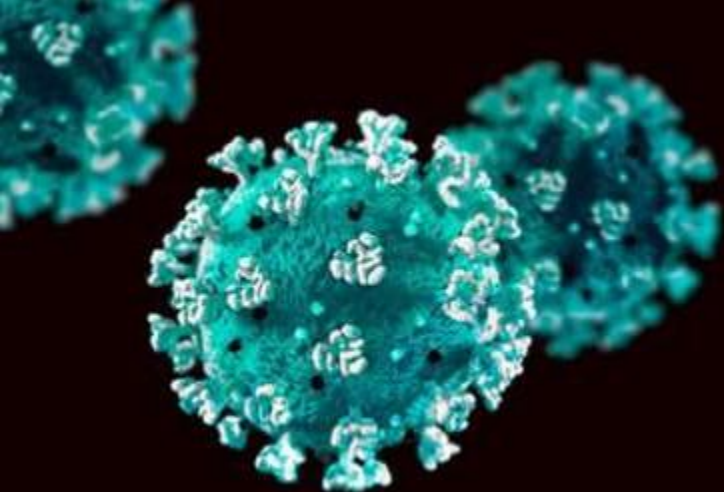




WE PROTECT YOU

YOU PROTECT OTHERS





Royax Medical
Solution

One of the biggest manufacturers of PPE
respirators and medical face masks in
Central Europe , Producing more than
10,000,000 units per month



COVID-19
CORONA VIRUS

ABOUT US

Royax Group of medical manufacturing companies has been producing medical equipment since 1973. The company objective is to manufacture and deliver medical equipment and products that contribute to saving lives.

Royax demonstrates enthusiasm and professionalism in the industry through its high-quality products and team of experienced design and production personnel. Innovation, including sole patent rights on various products, has been key to Royax's growth and longevity. Royax products satisfy all relevant international standards: EN 1789, EN 1865, ISO 13485 and CE according to EU- Medical Device Regulation 2017/745 And EN 149:2001 + A1:2009 Partly , PPE (EU) 2016/425 .



In response to the COVID-19 pandemic and the ongoing public health threats it poses, since March 2020 Royax has been able to mass-produce PPE and medical masks.

In a constant effort to save lives, Royax is now one of the largest manufacturers of respirators as Personal Protective Equipment and face masks in the whole Central European region with production capacity of more than 10,000,000 units per month.

Royax has all types of respirators and face masks tested by accredited laboratories in the Czech Republic and other European Union Member States in accordance with EN 149:2001+A:2009, EN 14683:2019+AC:2019. “Royax” brand respirators and face masks complied And Certified with CE regulations of Europe by VUBP Notify Body , as well as Council Directive PPE (EU) 2016/425 And EU Medical Devices Regulation 2017/745 of the European Parliament and of the Council.





FFP2 Respirator

This respirator is recommended for Health Care Providers (HCP)
Our respirator is designed to protect against living organisms such as
viruses, bacteria, fungi and hazardous particles

Made in Czech Republic





FFP3 Respirator

The FFP3 respirator is recommended for Health Care Providers (HCP) In close and direct contact with confirmed case of COVID 19 Our respirator is fitting to the face and with high quality and high tech material is able to meet higher filtration level and provide excellent protection

Made in Czech Republic



Made of high quality European raw materials

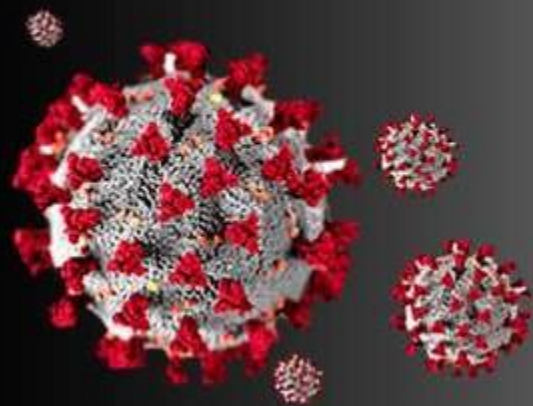
- Perfect fitting providing maximum comfort
- Easy to breathe
- Skin friendly and hypoallergenic
- High quality and high performance filtration





Our respirators are designed to protect you against viruses (COVID-19), bacteria, fungi and hazardous particles





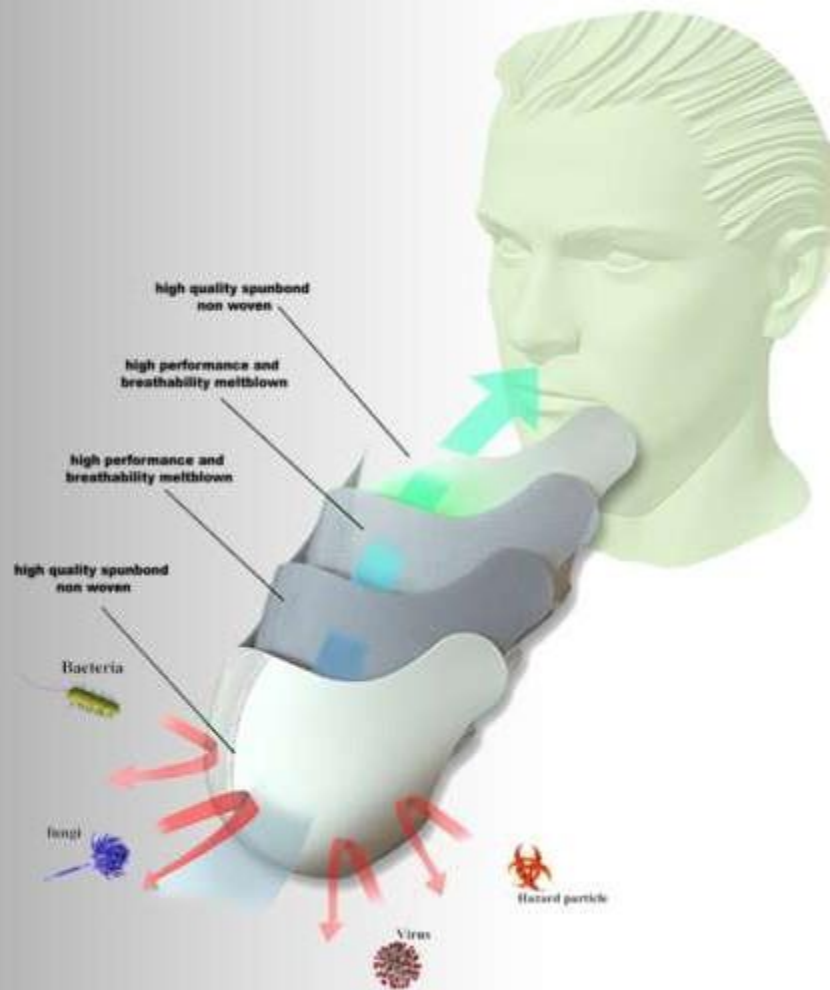
COVID-19

CORONA VIRUS

RoyaX Medical
Solution

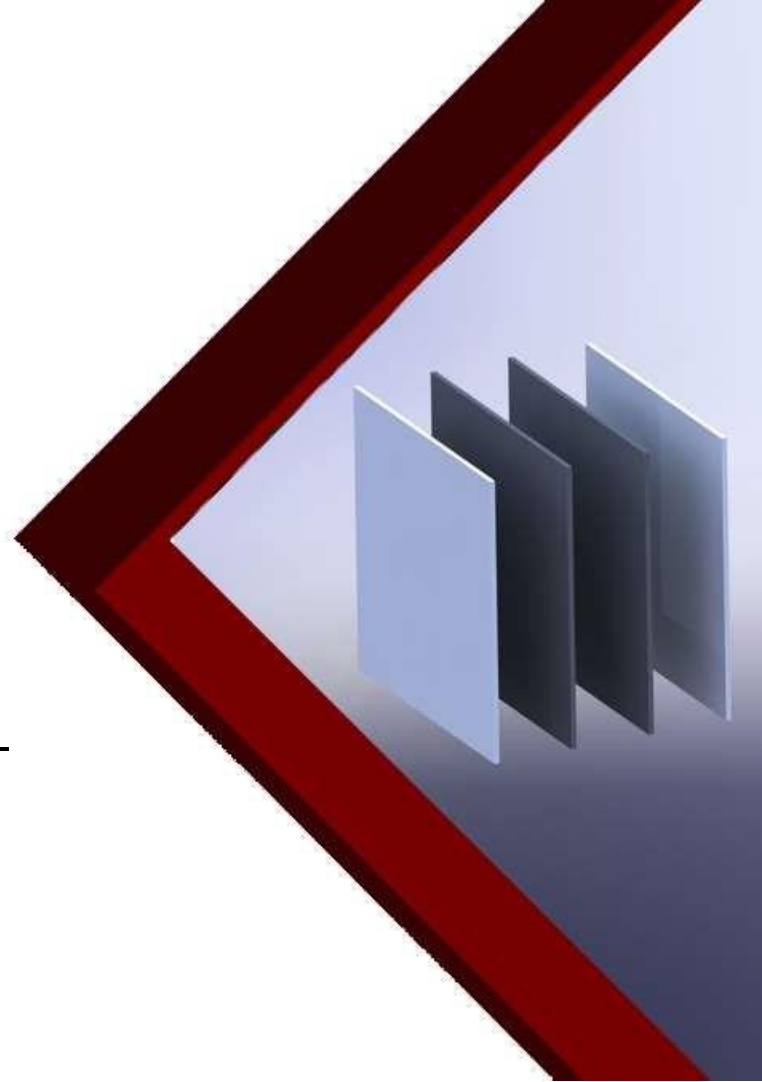
CE
1024

Tested and Certified products according to
EN149: 2001 + A1:2009
(EU) commission 2020/403 of 13 March 2020
on conformity assessment and market surveillance procedures within
the context of the COVID-19 Threat.





The respirators consist of 4-layers of high-quality spunbond fabrics and outstanding performance melt-blown filtering fabrics.





Výzkumný ústav bezpečnosti práce, v.v.i
Jeruzalémská 1283/9, 110 00 Praha 1
Oznámený subjekt č. 1024 – Notified Body 1024



vydává

CERTIFIKÁT EU PŘEZKOUŠENÍ TYPU č. 1024/E-139/2020

výrobci: ROYAX s.r.o., Obchodní 107, 251 01 Čestlice, Česká republika
identifikační číslo: IČ: 24755346 DIČ: CZ24755346
na výrobek: Respirator face mask
typ: R-DP-R-FFP3-01

Certifikát byl potvrzeno, že výše uvedený osobní ochranný prostředek, včetně příslušné technické dokumentace, je v souladu s příslušnými základními požadavky na ochranu zdraví a bezpečnost uvedenými v nařízení Evropského parlamentu a Rady (EU) 2016/425 o osobních ochranných prostředcích a o zrušení směrnice Rady 89/686/EHS, jak je uvedeno v závěrečné zprávě o certifikaci č. 1024/ZZ-114/2020, která je nedílnou součástí tohoto certifikátu.

Pro posouzení shody byly použity tyto harmonizované normy/specifikace:

ČSN EN 149:2002 +A1:2009 Ochranné prostředky dýchacích orgánů. Filtrační polomasky k ochraně proti částicím. Požadavky, zkoušení a značení
ČSN EN 149+A1 OPRAVA 1:2018 (dt. EN 149:2001+A1:2009)

Certifikace byla provedena podle certifikačního schématu nařízení (EU) 2016/425 modul B. Značení a návod na používání byl posuzován pouze v anglickém jazyce.

Tento certifikát je platný do 16. 12. 2025.

Jménem Výzkumného ústavu bezpečnosti práce, v. v. i. oznámeného subjektu 1024

V Praze dne 16. 12. 2020


Ing. Jiri Tihon, Ph.D., LL.M.

Výzkumný ústav bezpečnosti práce, v.v.i
Jeruzalémská 1283/9, 110 00 Praha 1
Oznámený subjekt č. 1024 – Notified Body 1024



vydává

CERTIFIKÁT EU PŘEZKOUŠENÍ TYPU č. 1024/E-015/2021

výrobci: ROYAX s.r.o., Obchodní 107, 251 01 Čestlice, Česká republika
identifikační číslo: IČ: 24755346 DIČ: CZ24755346
na výrobek: Respirator face mask
typ: R-DP-R-FFP2-01

Certifikát byl potvrzeno, že výše uvedený osobní ochranný prostředek, včetně příslušné technické dokumentace, je v souladu s příslušnými základními požadavky na ochranu zdraví a bezpečnost uvedenými v nařízení Evropského parlamentu a Rady (EU) 2016/425 o osobních ochranných prostředcích a o zrušení směrnice Rady 89/686/EHS, jak je uvedeno v závěrečné zprávě o certifikaci č. 1024/ZZ-015/2021, která je nedílnou součástí tohoto certifikátu.

Pro posouzení shody byly použity tyto harmonizované normy/specifikace:

ČSN EN 149:2002 +A1:2009 Ochranné prostředky dýchacích orgánů. Filtrační polomasky k ochraně proti částicím. Požadavky, zkoušení a značení (dt. EN 149:2001+A1:2009)
ČSN EN 149+A1 OPRAVA 1:2018

Certifikace byla provedena podle certifikačního schématu nařízení (EU) 2016/425 modul B. Značení a návod na používání byl posuzován pouze v anglickém jazyce.

Tento certifikát je platný do 12. 2. 2026.

Jménem Výzkumného ústavu bezpečnosti práce, v. v. i. oznámeného subjektu 1024

V Praze dne 12. 2. 2021


Ing. Jiri Tihon, Ph.D., LL.M.

Test reports and Certificates



Occupational Safety Research Institute, v.v.i.

Notified Body 1024

Jeruzalémská 1283/9, CZ - 110 00 Praha 1

Test Report according to Regulation (EU) 2016/425 *

Report on product check according to Module C2

1024/ZK-037/2024

Pages: 5 Number of copies: see distribution list
Annexes: 0

I. Source data

Name: **Respiratory face mask**
Type: **R-DP-R-FFP3-01**
PPE category: III. according to Regulation (EU) 2016/425 Annex I
Manufacturer: ROYAX s.r.o., Újezdská 310, 257 44 Netvořice
Application: S-199/2024 dated: 01. 10. 2024
Contract: 092/2024 dated: 15. 10. 2024
Certificate: 1024/E-139/2020 dated: 16. 12. 2020

Assessed by: Ing. J. Foud

Certificate remains valid

About continued validity of certificate decided: Ing. J. Tíhon, Ph.D., LL.M.

Date of report issue: 19. 11. 2024

Distribution list: 1. Manufacturer
2. NB 1024 archive in electronic form (PDF)

The product check was performed according to Regulation (EU) 2016/425, Module C2 Conformity to type based on internal production control plus supervised product checks at random intervals

*This Report has been issued in Czech and English versions. Both versions have the same validity.



OSRI, v.v.i.

Notified Body 1024

Jeruzalémská 1283/9, CZ - 110 00 Praha 1

Phone: +420 221 015 811

www.vubp.cz

E-mail: NB1024@vubp.cz

II. Basic information

1. Product description
Respirator face mask R-DP-R-FFP3-01 FFP3 NR provides the protection of the respiratory system of a user against solid and liquid aerosols in accordance with the information supplied by the manufacturer.

The manufacturer has changed the address of its registered office and production from "Obchodní 107, 251 01 Čestice" to "Újezdská 310, 257 44 Netvořice". The product has not yet been manufactured at the new address.

2. Sample withdrawal

Samples of the filtering half mask R-DP-R-FFP3-01 FFP3 NR for laboratory tests were taken on 9th October 2024 in the number of 10 pieces of size L. The samples were registered in the Laboratory Register under numbers 962 - 971.

III. List of submitted technical documentation

According to Regulation (EU) 2016/425 Annex III.

a) a complete description of the PPE and of its intended use	+
b) an assessment of the risks against which the PPE is intended to protect	+
c) a list of the essential health and safety requirements that are applicable to the PPE	+
d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits	+
e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE	0
f) the references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied	+
g) where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements	0
h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements	+
i) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class	+
j) a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications	+
k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II	+
l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model	0
m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements	0



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Evaluation: + available, range is satisfactory; - requirement not fulfilled; 0 not applicable
The submitted technical documentation was found to be complete according to Regulation (EU) 2016/425 ANNEX III and it has been adequate for the assessment of the conformity with the technical requirements mentioned in this Regulation.

IV. Level determination of protective properties and safety function of the product

The Certificate no. 1024/E-139/2020 has been issued on the product. The measurement results are described in the Final report no. 1024/ZZ-114/2020.

The check of the PPE conformity with the certified type was performed according to EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks. Requirements, testing, marking (ed. CSN EN 149:2002+A1:2009 on the basis of the Application no. S-199/2024 and the Contract no. 092/2024.

The selected tests on the samples were carried out according to CSN EN 149:2002+A1:2009).

8.3.2	temperature conditioning
8.3.3	mechanical strength
8.9.1	inhalation resistance
8.9.2	exhalation resistance
8.11	penetration of filter material - NaCl aerosol

The numbering of articles in the paragraph "Test results" is consistent with the above-mentioned standard numbering.

V. Tests results

7.5 Material

Requirement: Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. After the temperature conditioning the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Discovered: After test of temperature resistance particle filtering half masks show no visible changes. After the mechanical resistance test, particle filtering half masks show no mechanical flaws.

Evaluation: Samples have satisfied the requirement

7.9.2 Penetration of filter material - aerosol NaCl

Requirement: The penetration of NaCl aerosol shall not exceed for class FFP3 the value of 1%
Discovered:

Initial penetration of NaCl aerosol

sample	condition	penetration %
962	MS+TC	0,07
963	MS+TC	0,09
964	MS+TC	0,07

Notice: MS - Mechanical strength
TC - Temperature conditioned

Test reports and Certifica



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The highest measured value of NaCl aerosol penetration

sample	condition	penetration %	time of the highest measured values min.
962	MS+TC	0.07	3
963	MS+TC	0.09	3
964	MS+TC	0.07	3

Evaluation: Samples have satisfied the requirement

7.16 Breathing resistance

Requirement: The inhalation resistance for class FFP3 shall not exceed 100 Pa at flow of 30 l/min and 300 Pa at flow of 95 l/min.

Discovered:

Inhalation resistance

sample	condition	resistance Pa	
		at 30 l/min	at 95 l/min
969	AR	69	234
970	AR	69	234
971	AR	65	228

Notes: AR - As received

Requirement: The exhalation resistance for classes FFP3 shall not exceed 300 Pa at flow of 160 l/min.

Discovered:

Exhalation resistance

sample	condition	position					
		ahead	down	up	left	right	
		Pa	Pa	Pa	Pa	Pa	
969	AR	300	300	300	300	300	
970	AR	300	300	300	300	300	
971	AR	300	300	300	300	300	

Evaluation: Samples have satisfied the requirement

Non-homogeneity checking of production

The non-homogeneity checking of the production was also carried out within the check. The client has chosen the procedure - once per year, take sufficient samples.

The non-homogeneity was not found within the check.

VI. Conformity assessment to the essential requirements

The relevant requirements referred to Regulation (EU) 2016/425 ANNEX II, applicable to the final product, were assessed. The harmonized standard EN 149:2001+A1:2009 has been used during the assessment.

The check has confirmed that the tested personal protective equipment

conforms to the type described in the Certificate no. 1024/E-139/2020

and continues to satisfy the relevant essential requirements of Regulation (EU) 2016/425, on personal protective equipment.



OSRI, v.v.i.
Notified Body 1024
Jeruzalémská 1283/9, CZ - 110 00 Praha 1

Phone: +420 221 015 811
www.vubp.cz
E-mail: NB1024@vubp.cz

VII. List of documents necessary for the Report elaboration

1. Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC
2. Application for check no. S-199/2024 dated 01. 10. 2024
3. Contract about check no. 092/2024 dated 15. 10. 2024
4. Test report no. 142/2024 dated 31. 10. 2024
5. Report no. 1024/ZK-114/2020 dated 16. 12. 2020
6. EU type examination certificate no. 1024/E-139/2020 dated 16. 12. 2020
7. Declarations of manufacturer, technical documentation
8. EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking (idt. CSN EN 149:2002+A1:2009, CSN EN 149+A1 OPRAVA 1:2018)





**We use laser marking on our masks and not conventional printing ,
so that no other potentially harmful matter is introduced.**

Roya^x Medical
Solution

Gallery Slides





Highest quality modern machinery is used at every stage of manufacturing and packaging .

RoyaX Medical
Solution

Gallery Slides