

Certificate

of EU type-examination No. UE/480/2020/1437, edition 5

Name of the product:

Filtering half mask

Type (varieties):

AM2 FFP2 NR
AM2 FFP2 NR D
AM2 BU FFP2 NR
AM2 BU FFP2 NR D

Name and address of the manufacturer:

EUROPROFIL Sp. z o.o.
Zielona 11
11-015 Olsztynek
Poland

**The product meets the applicable essential health and safety requirements
included in Regulation (EU) 2016/425 of the European Parliament and of the Council
of 9 March 2016**

Validity period: from 8 December 2021 to 25 October 2025

Head of the Centre
for Certification of Personal
Protective and Working Equipment

A. Steffo
Agnieszka Steffo M.Sc.(Eng.)

.....
signature of the certificate issuer's representative

Warsaw, date 8 December 2021

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Product description:

The filtering half mask type AM2 FFP2 NR, AM2 FFP2 NR D, AM2 BU FFP2 NR and AM2 BU FFP2 NR D is a one-way half mask in which the air flows through the filtering material in the inhalation and the exhalation phase. It is a complete respiratory protective device to protect against solid and liquid aerosols. The filtering half mask type AM2 FFP2 NR is available in sizes M, L and S, the filtering half mask type AM2 FFP2 NR D, AM2 BU FFP2 NR and AM2 BU FFP2 NR D is available in sizes M and L.

The bowl of the filtering half mask consists of the following nonwoven fabric layers:

- the outer layer:
 - the polypropylene spunbond material with the surface mass of 60 g/m^2 ,
- the middle layer:
 - two layers of the filtering polypropylene material, each with the surface mass of 19 g/m^2 ,
- the inner layer:
 - the polypropylene spunbond material with the surface mass of 20 g/m^2 .

The filtering half mask is fitted with:

- the nose clip made of plastic, reinforced with two wires,
- two earloops made of textile rubber,
- a polypropylene clasp for fastening straps on the back of the head (AM2 FFP2 NR, AM2 FFP2 NR D),
- the nose seal made of the polyethylene foam (AM2 FFP2 NR, AM2 FFP2 NR D).

Image:



type AM2 FFP2 NR (L)



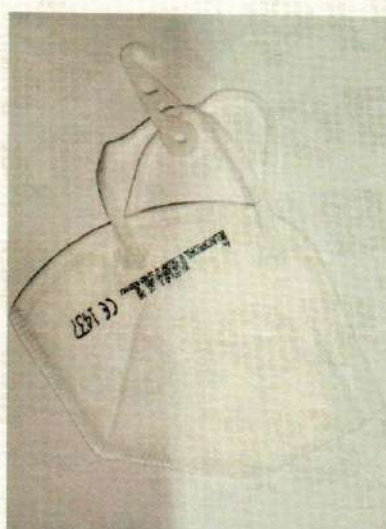
type AM2 FFP2 NR (M)



type AM2 FFP2 NR (S)



type AM2 FFP2 NR D (L)



type AM2 FFP2 NR D (M)



type AM2 BU FFP2 NR (L)



type AM2 BU FFP2 NR (M)



type AM2 BU FFP2 NR D (L)



type AM2 BU FFP2 NR D (M)

Basic parameters:

class, personal protective equipment category, performance level(s) or protection class of the product

- penetration of sodium chloride aerosol - protection class FFP2 NR
- penetration of paraffin oil mist aerosol - protection class FFP2 NR
- breathing resistance - protection class FFP2 NR
- total inward leakage - protection class FFP2 NR
- clogging - protection class FFP2 D (for the Filtering half mask type AM2 FFP2 NR D, AM2 BU FFP2 NR D)
- limited to a single shift use only - NR

Identification of the submitted documentation:

- application for EU type-examination No. 834/2021 dated 22.11.2021
- agreement on EU type-examination and review of the EU type-examination certificate No. 172/2020/1437, dated 07.10.2020
- technical documentation of the Filtering half mask AM 2 FFP2 NR and AM 2 FFP2 NR D No. DT-01 Edition 2, dated 25.06.2021 + update dated 15.11.2021
- declaration of harmlessness of materials used dated 15.11.2021
- user instruction dated 15.11.2021

**Product/product model supplied with the EU type-examination application
is compliant with the technical documentation.**

The product meets the requirements of harmonised standard/technical specifications:

EN 149:2001+A1:2009 "Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking"

confirmed by tests performed by:

CIOP-PIB, Department of Personal Protective Equipment, Lodz, Poland

report No.:

1218/PB-COV/2020/NO dated 26.10.2020, 1581/PB-COV/2020/NO dated 08.01.2021,
274/PB-COV/2021/NO dated 16.04.2021, 473/PB-COV/2021/NO dated 18.06.2021,
844/PB-COV/2021/NO dated 08.11.2021

Marking:

logo and address of the manufacturer: EUROPROFIL Sp. z o.o.; product identification type: AM 2 or AM2 BU; protection class: FFP2 NR or FFP2 NR D; standard: EN 149:2001+A1:2009; the batch number; size

The certificate applies in conjunction with one of procedures of conformity assessment according to C2 module or D module pursuant to Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016

NOTE 1:

Every modification to the product and its technical documentation to which this certificate pertains should be notified to the Centre for Certification of Personal Protective and Working Equipment of the Central Institute for Labour Protection – National Research Institute.

This certificate shall be valid as long as the above harmonised standard may be applied as a basis for product examination.

NOTE 2:

Forging the content and the markings of the certificate or modifying them (including a photocopy or scan), or using such document as authentic is a crime under Article 270 § 1 of the Criminal Code.



EU DECLARATION OF CONFORMITY

1. **Medical device / Medical filtering half mask AM2 FFP2 NR, class I, code Basic UDI- DI 5903771861MasksSA**
2. Manufacturer's name and address:
Europrofil SP. z o.o.
Ul. Zielona 11
11 – 015 Olsztynek
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Europrofil Sp. z o.o., ul. Zielona 11, 11-015 Olsztynek, POLAND
4. Object of the declaration: The AM2 FFP2 NR medical respirator, class I, is designed to protect the respiratory system against aerosols made of solid and liquid particles, including infectious agents.
5. Described in point 4 the subject of this declaration complies with the relevant requirements of the Union harmonization legislation: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83 / EC, Regulation (EC) No 178/2002 and Regulation (EC) 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686 / EEC. It also meets the requirements of the PN-EN 149: 2001 + A1: 2009 standard, which have been confirmed by the EU / 480/2020/1437 type examination certificate of 04.08.2021 issued by the notified body - Central Institute of Work - National Research Institute, ul. Czerniakowska 16, 00-701 Warsaw, unit number 1437
6. The half-mask is a class I medical device according to rule 1 in accordance with Annex VIII of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amendments to Directive 2001/83 / EC, Regulation (EC) 178/2002 and Regulation (EC) 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC. In addition, the product is also a personal protective equipment of category III and is subject to the type conformity assessment procedure, based on supervised product checks at random intervals (module C2), under the supervision of a notified body - Central Institute of Work - National Research Institute, ul. Czerniakowska 16, 00-701 Warsaw, unit number 1437
7. The products are manufactured in accordance with the requirements of standards for medical devices and applicable legal regulations.
8. The products meet the applicable requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, including CE marking.
9. The AM2 FFP2 NR medical filtering half-mask designed to protect the respiratory system against aerosols from solid and liquid particles, including infectious agents, is a class I medical device according to rule 1 and is subject to conformity assessment on the basis of the following standards: PN-EN 14683 + AC: 2019-09, PN-EN ISO 14971: 2012, PN-EN 1041 + A1: 2013-12, PN-EN ISO 10993-1: 2010, PN-EN ISO 15223-1: 2017-02. The filtering half mask has been tested for compliance with the EN 14683: 2019 + AC standard for the efficiency of filtration of bacterial strains, microbiological purity, breathing resistance and resistance to splashes for type IIR. In terms of filtration efficiency and microbiological purity, the product meets the requirements for type I, II and IIR medical masks. In terms of breathing resistance and splash resistance, the product meets the requirements for type IIR medical masks.
10. The medical filtering half mask AM2 FFP2 NR also meets the requirements of §221 point. 1) and 2) of the Regulation of the Minister of Energy of 23 November 2016 on the detailed requirements for the operation of underground mining plants: "It is unacceptable to use personal protective equipment, work clothing and footwear that can: 1) be a source of spark or electric arc, caused by static electricity or a shock, 2) ignite an explosive mixture "(Journal of Laws 2017, item 1118.

Olsztynek, 04.08.2021

EUROPROFIL Sp. z o.o.
ul. Zielona 11, 11-015 Olsztynek
tel. 89 512 32 22
NIP. 8361732941 REGON: 750806455

(imię i nazwisko, stanowisko)
Poimonożnik ds. ZKP

Natalia Matychowska

EUROPROFIL

tel. +48 89 512 32 22

faks +48 89 512 05 33

sekretariat@europrofil.co

www.europrofil.co

naszemaseczki.pl

tel. +48 89 511 85 11

faks +48 89 512 05 33

sklep@naszemaseczki.pl

www.naszemaseczki.pl

CENTRAL INSTITUTE FOR LABOUR PROTECTION
- NATIONAL RESEARCH INSTITUTE
Centre for Certification of Personal
Protective and Working Equipment

Poland, 90-133 Łódź, ul. Wierzbowa 48
phone: (+48) 42 648 02 44, fax (+48) 42 648 02 48

Date: 26.01.2022

Ref. No.: SO/37/2022

(SO.542.834.2021.B)

(SO.542.596.2020.B)

EUROPROFIL Sp. z o.o.
Zielona 11
11-015 Olsztynek

concerns the EU type-examination certificates Nos.:
UE/480/2020/1437 Ed. 5 and UE/533/2021/1437 Ed. 1

Dear Sir or Madam,

in reply to your letter of 21st January 2022 regarding the approval of the outer layer of Spunbond nonwoven fabric in a color different than the one approved in the certification process to be used in "Filtering half masks type AM2 FFP2 NR, AM2 FFP2 NR D, AM2 BU FFP2 NR and AM2 BU FFP2 NR D" as well as "Filtering half mask type AM3 FFP3 NR", being the subject of the abovementioned certificates, we would like to inform you that we agree to the proposed alternative solution.

The modification to the color of the nonwoven fabric, provided that the material composition and the surface mass remain the same, does not change filtration and protective properties of the products in question.

We would also like to inform that your letter notifying the modification has been attached to the documentation of certificates No. UE/480/2020/1437 Edition 5 and UE/533/2021/1437 Edition 1, stored in CIOP-PIB, whereas the information on the application of different colors of half masks may be included in the certificates in case of the necessity to carry out their next review.

Yours faithfully,

Head of the Centre
for Certification of Personal
Protective and Working Equipment

A. Stefko
Agnieszka Stefko M.Sc.(Eng.)

Date: 14.01.2022

Ref: SO.542.01.2022.C2.18

Poland, 90-133 Łódź, ul. Wierzbowa 48
phone: (+48) 42 648 02 44, fax (+48) 42 648 02 48**Ms Aneta Biernat**
President
Europrofil Sp. z o.o.
ul. Zielona 11
11-015 Olsztynek

Dear Ms Biernat,

With reference to the product inspection carried out under contract No. C2/18/2020/1437 under derogation conditions in accordance with Module C2 of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016, please find enclosed the inspection report.

As a result of the inspection, we confirm that the tested samples of filtering half masks AM2 FFP2 NR, AM2 FFP2 NR D, AM2 BU FFP2 NR, AM2 BU FFP2 NR D covered by CIOP-PIB certificate (No. EU/480/2020/1437, issue 5) meet the requirements set out in the harmonized standard on which their assessment is based and correspond to the type described in the above mentioned certificate.

We therefore confirm that the above products meet the applicable essential health and safety requirements according to Regulation (EU) 2016/425.

Considering the positive outcome of the inspection, we hereby confirm that manufacturing process of the products covered by the above-mentioned certificates ensures the homogeneity of production.

Sincerely yours,

Head of the Centre
for Certification of Personal
Protective and Working Equipment
A. Stefko
Agnieszka Stefko M.Sc.(Eng.)