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

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(imię i nazwisko, stanowisko)
Pełnomocnik ds. ZKP
(podpis)
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