



Led ve Ses Teknolojileri

19.04.2021

EU DECLARATION OF CONFORMITY

MANUFACTURER

YILDIRIM LED VE SES TEKNOLOJİLERİ SAN. TİC. LTD. ŞTİ.

Fener Mah. Bülent Ecevit Bulvarı No:48 Yıldırım Plaza Muratpaşa ANTALYA / TURKEY

PRODUCT DESCRIPTION

Model : ESZE F2

Filtering Half Mask

Class: FFP2 NR

Particle Filtering Half Face Mask in Category III product according to (EU) 2016/425 Personal Protective Equipment Regulation

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- Complies with EU 2016/425 Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Essential Health and Safety Requirements of Technical harmonized standard EN 149:2001 +A1:2009
- All required tests referred in above standards are conducted,
- Complies with other relevant harmonized legislation and community standards
- For the assessment of conformity the EU Type Examination Certificate (Serial No: 151-21-01) is issued, after all technical evaluations for conformity to regulation and harmonized standards conducted, by; MNA LABORATORIES IND.TRADE.CO.LTD., as Notified Body number 2841
- The PPE is subject to the conformity assessment procedure to conformity to type based on internal production control plus supervised products checks at random intervals in accordance with Module C2 (Report No: 151-21-01-01) of the regulation 2016/425 under surveillance of the notified body number 2841

MARKING, LABELLING

Marking, labelling and user information are prepared in accordance with EU 2016/425 Personal Protective Equipment Regulation and the harmonized product standards given above.

MEASURES TO ENSURE CONFORMITY

The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

ZEKERİYA YILDIRIM

General Manager

Antaya 19/04/2021

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