

EU DECLARATION OF CONFORMITY

MANUFACTURER

MONDO MEDICAL DIS TICARET
ABDURRAHMAN NAFIZ GURMAN MAH.TURUCLU SOK.MESA PLAZA NO:25 IC
KAPI NO:2 / GUNGOREN / ISTANBUL
TURKEY

PRODUCT DESCRIPTION

Brand name: MONDO Model: M001
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 Manufacturer, safe and meets all the necessary legal conditions and requirements. The product is a personal protective equipment that is intended for single use and solely in accordance with the Manufacturer's instructions.

The Conformity is ensured with the following mechanism:

- 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 testes referred in above standards are conducted,
- For the assessment of conformity the EU Type Examination certificate (Serial No: 92-20-03) is issued after all technical evaluations for conformity to the regulation and harmonized standards conducted, by:
 - MNA LAB SAN TIC LTD STI, as Notified Body number 2841
- The product is under surveillance of same Notified Body, NB 2841 according to the Annex III (Module C2) of the PPE Regulation (EU) 2016/425, for quality assurance.

MARKING, LABELLING

Marking, labelling and used 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 declared that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and technical requirements for this type of product.

