

EU DECLARATION OF CONFORMITY

MANUFACTURER

FAGO MEDİKAL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
15 Temmuz Mahallesi Cami Yolu Caddesi No:106 İç Kapı No: Z1 Bağcılar İSTANBUL /
TURKEY

PRODUCT DESCRIPTION

Model: FAGO 101
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 harmonised 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:2163-PPE-1270) is issued, after all technical evaluations for conformity to the regulation and harmonised standards conducted, by:
 - UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co, as Notified Body number 2163
- The product is under surveillance of same Notified Body, NB 2163 according to the Annex III (Module C2) of the PPE Regulation (EU) 2016/425, for quality assurance.

MARKING, LABELLING

Marking, labelling and user information are prepared in accordance with EU 2016/425 Personal Protective Equipment Regulation and the harmonised 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 technical requirements for this type of product.

GÖKHAN AYDIN

General Manager

13/08/2020

FAGO MEDİKAL SAN. ve TİC. LTD. ŞTİ.
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