EU DECLARATION OF CONFORMITY MDD 098

PRODUCER

İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET ANONİM ŞİRKETİ
Orhangazi Mahallesi Tunç Caddesi No:5 34538 Esenyurt / İSTANBUL

PRODUCT DESCRIPTION

Layered and molded medical device classified in the class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Brand Name : A&Z MED
Model : OLI - 2022
Type II

This declaration of conformity is issued under the sole responsibility of the manufacturer:
The Producer / 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 Producer's / the Manufacturer's instructions.

The notified body Universal Certification and Surveillance Service Trade Ltd. Co., Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No: 44/84 Yukarı Dudullu, Ümraniye-Istanbul, Turkey, number MDD 098, performed the EU type examination (Module B) and issued the EU type-examination certificate number MDD 098

The PPE is subject to the conformity assessment procedure based on internal production control plus supervised product checks at random intervals (Module C2) set out in the Regulation (EU) 2016/425, under surveillance of the notified body Universal Certification and Surveillance Service Trade Ltd. Co., number MDD 098.

The Conformity is assessed especially with the following provisions:

- Government Regulation no. 93/42/EEC Medical devices establishing technical requirements for medical devices, in effective wording
- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
- Other relevant harmonized legislation
- Other relevant local, national and community standards
- For the assessment of conformity, the following documents were also applied to:
- Tests for irritation and delayed-type hypersensitivity
- Results of laboratory tests Ekoteks Testing Laboratory BFE
- Results of laboratory tests Ekoteks Testing Laboratory Differential Pressure
- Results of laboratory tests Ekoteks Testing Laboratory Microbial Cleanliness

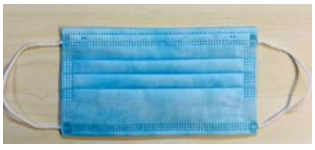
MARKİNG, LABELLİNG

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied: type of mask (as indicated in Table 1).
EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered

MEASURES TO ENSURE CONFORMITY

The Producer / 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.

This certificate is issued on 04/05/2020 and valid until 03/05/2021 with the conditions that no change has been made with the product reference and no change in productions process or not suspended or withdraw for any reason.



Olgun İBİŞ
Chief Executive Officer
04.05.2020- İstanbul

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