

ATTESTATION OF CONFORMITY

Certificate No: MD-378

İBİŞLER TEKSTİL SAN. VE DİŞ TİC. A.Ş.
Orhangazi mh. Tunç Cad. No:5/B Esenyurt/İstanbul / TURKEY

The manufacturer's technical documentation (Dated 01.08.2021), manufacturing facilities and the product, identified below, found to meet the applicable requirements of Regulation (EU) 2017/745 for Class I devices, including the General Safety and Performance Requirements in Annex I of the regulation based on assessment results and evaluation of relevant test reports.

Identification of the Product

Brand Name: A&Z MED, Model: OLI-2026

UDI-DI Number: 8682742OLI2026YU

Classification: Type IIR

Medical masks, as a medical device, manufactured from spunbound and meltblown fabrics, with ear loops and nose bridge. The mask is available in 1 size and white colour.

For more details, refer to the evaluation report provided to the manufacturer, dated 28.12.2021 and number MD-TR-378.

The following harmonised standards have been applied:

EN 14683+AC:2019, Medical face masks - Requirements and test methods.

This certification is based on the voluntary scheme for verification of obligations fulfilled by the manufacturer according to Class I product requirements defined in the medical device regulation EU 2017/745 to fix the CE mark on the product, identified above. The manufacturer shall also issue an appropriate EU Declaration of Conformity according to Medical Devices regulation (EU) 2017/745 Annex IV.

This certificate is initially issued on **28/12/2021**, will be valid for 1 year from the issue date, without any change in the design and manufacturing process of the product.

İSTANBUL – 28.12.2021



Verify the validity with the QR Code



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director