



# EUROTECH CERTIFICATION

## Conformity Certificate

### Statement Of Compliance

No: SC/2020033

Has been assessed as meeting the Essential Requirements and relevant provisions of EC Directive 93/42/EEC Annex I as amended by 2007/47/EC for Medical Devices

**Disposable Non Woven Face Mask (Non-sterile - 2 Ply, 3 Ply)**  
**(Class I not sterile or measuring via Annex IX Rule I)**  
Face masks being used for patient protection (MDD Class I)

manufactured by the company:

**ALFA PROMOSYON TEKSTIL PAZARLAMA SANAYI VE TICARET ANONIM SIRKETI**  
**Mehmet Akif Mah. Kemalpaşa Cad. Alfa Tekstil No: 88 İc Kapi No: 3 Kucukcekmece/**  
**ISTANBUL/TURKEY**

Complies to the applicable essential requirements of EC Directive 93/42/EEC Annex I as amended by 2007/47/EC for Medical Devices on medical device products as amended that have been implemented into the following harmonized European Standard and directive:

*93/42/EEC and 2007/47/EC - Medical device directive*

*ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes*

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

Taking into account the intended use, the EUROTECH Product Certification body has conducted, with successful results of the certified product according to relevant parts of the above mentioned Directives and European standards. This certificate is Declaration of Conformity issued by Authorized Representative, it is not NB Certificate.

The product description, technical documentation, assessment procedures and evaluation of the products are conforms with the standard and directive requirements.

*After fulfilling the relevant directive requirements, the manufacturer shall affix to each Product, of the above referenced models, the CE marking according to this example:*



Date of issue: March 23, 2020

Date of expiration: March 23, 2023

