

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-205

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993,

the products manufactured by

AKFE TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

at the following address

Yeşilcami Mahallesi Sanayi Caddesi Cevteks Çarşı Apartmanı No: 64/59 İznik / Bursa / TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name: CEV-MED

Model: ESC 04

Classification: Type II

are tested according to the following initial type tests by the manufacturer

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

For the assessment of conformity, the following documents were also applied to:

Results of laboratory tests Ekoteks Testing Laboratory BFE, Microbial Cleanliness, Differential Pressure

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the medical face masks manufactured and designed for use during the medical operations or similar medical situations with same requirements which require restriction of infectious materials to be spread to patients. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; reference to EN 14683 standard, type of mask (as indicated in Table 1) and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 30/07/2020 and valid until 29/07/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

ISTANBUL – 30/07/2020



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Genel Müdür



Verify the validity with the QR Code



EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1320

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Akfe Tekstil Sanayi ve Ticaret Limited Şirketi

Yeşilcami Mah. Sanayi Cad. Gökhan Akay Apt. No:32/A İç Kapı No:10 İznik Bursa TURKEY

are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices -
Filtering Half Masks to Protect Against Particles -
Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: CEV-MED **Model:** ESC-03

Filtering half mask

Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **20/08/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director