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CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-329

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 Commission directive 2007/47/EEC amending Medical Devices Directive dated 05 September 2007,

the products manufactured by

FAGO MEDİKAL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

at the following address

15 Temmuz Mah. Cami Yolu Cad. No: 106 / Z1 Bağcılar ISTANBUL / TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name: FAMEX
Model: FG3
Type IIR
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 Laboratuvar Testing Laboratory Bacterial Filtration Efficiency, Microbial Cleanliness, Differential Pressure and Splash Resistance Pressure tests.

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 11/12/2020 and valid until 10/12/2021 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 – 11/12/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
General Manager

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be concuted annually following the surveillance audits, updating the publicationdate without changing the certificate [illegible]

EU DECLARATION OF CONFORMITY

MANUFACTURER
FAGO MEDİKAL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
15 Temmuz Mah. Cami Yolu Cad. No: 106 / Z1 Bağcılar ISTANBUL / TURKEY

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: FAMEX
Model: FG3
Type IIR

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 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 Laboratuvar Testing Laboratory Bavterial filtration efficiency
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Microbial Cleanliness
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Differential Pressure
- Results of laboratory tests Ekoteks Laboratuvar Testing Laboratory Splash Resistance Pressure

MARKING, LABELLING

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.

CE

General Manager
11/12/2020

FAGO MEDİKAL SAN. ve TİC. LTD. ŞTİ.
15 Temmuz Mh. Cami Yolu Cd. No:106/Z1
Bağcılar/İSTANBUL Sic.No: 344684-5
Güneşli V.D.: 3840738071

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TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 11.12.2020 / 12-2020-T0567

Manufacturer: FAGO MEDİKAL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Address: 15 Temmuz Mah. Cami Yolu Cad. No: 106 / Z1 Bağcılar ISTANBUL / TURKEY

The medikal masks manufactured by the above manufacturer, are evaluated based on the Annex ZA of harmonised standard EN 14683/AC:2019 and the essential health and Safety requirements of 93/42/EEC, Medical Device Directive for Class I products on avoluntary base upon the manufacturer request.

Product Description: Medical Face Mask
Trademark: FAMEX **Model:** FG3

As a third party evaluation, the technical file provided by the manufacturer is evaluated and the samples provided by the manufacturer are tested according to Annex ZA of the EN 14683/AC:2019 standard.

See Annex I: Test report provided by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş. 30.10.2020, 20039572 date and with report number.

This report or the issued certificate, in case the report is positive, does not take over orchange the sole reponsibility of the manufacturer covered under 93/42/EEC Medical Device Directive. The manufacturer shall fulfil all responsibilities for Class I products under 93/42/EEC Medical Device Directive.

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The results of the evaluation are as follows;

A- Review of the technical file

The manufacturer owns a technical file based on the requirements of 93/42/EEC Medical Device Directive in which the essential health and Safety requirements for Class I products are handled and have documented procedures to fulfil these requirements. The positive result of this report or the possible certificate to be issued based on positive result of this report shall not be used as the share of the responsibility of manufacturer on the fulfilment of any responsibility to be fulfilled before putting the product on the EU market.

B- Product Test Results

The tests referenced in Annex ZA are conducted on the samples provided by the manufacturer and the results are evaluated;

1. **Biocompatibility**

In the evaluation of the technical file, it was observed that the manufacturer has established a mechanism for the evaluation of raw materials or semi-finished goods on their biocompatibility. The manufacturer claims that the request and evaluation of proofs for biocompatiblity of the goods is an essential part of the procurement policy and declares that the produced masks are complies with the biocompatibility requirements and have authorised responsible staff members for ensuring the success of this policy. It is considered that the manufacturer have an effective policy for the biocompatibility of the product.

2. **Bacteria Filtration Efficiency**

At least 5 samples are subjected to a bacteria aerosol with a flow rate of 28.3 L/min for 2 minutes with a test setup defined in the Annex B of EN 14683/AC:2019 standard. With the results of the incubation of samples taken in different particule sizes are shown in the annexed test report.

The minimum bacteria filtration efficiency performance required by each performance classes are shown below;

Test	Type I*	Type II	Type IIR
Bacterial Filtration Efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
* Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.			

According to the evaluation of the results of 5 samples tested, the minimum bacteria filtration efficiency is given as **98,0 %**. According to this result, the bacteria filtration efficiency performance of the masks is classifified as **Type IIR**.

It was observed that the avarage positive control values and negative control value is also reported as a confidence parameter of the test result are meaningful.

3. **Microbial Cleanliness (Bioburden)**

It is expected to have the number of colony forming units per gram to be lower than 30 for all performance class of masks according to the test result based on ISO 11737-1 standard.

In the evaluation of the test result, the maximum count of the colony forming unit is reported as **<30** For this test result the samples complies the requirement for all performance classes (Type I, Type II and Type IIR).

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4. **Differentail Pressure**

The test is conducted to measure the breathing resistance as the differantial pressure and the expected result for Type I and Type II classes is not to be higher than 40 Pa/cm^2 and for Type IIR class not to be higher than 60 Pa/cm^2.

According to the test results, the highest differantial pressure measured is **31,8** Pa/cm^2 and the samples complies the requirement for all performance classes (Type I, Type II and Type IIR).

5. **Splash Resistance Pressure**

In the test, done according to ISO 22609:2004 the product's splash resistance is expected to be equal or higher than 16kpa for the Type 2R class.

All 15 samples tested were able to provide Type IIR performances as 16kPa resistance.

C- Summary and Conclusion

Evaluation	Requirement	Result	Classification
Bacterial Filtration Efficiency (BFE), (%)	≥ 95 % – Type I ≥ 98 % – Type II ≥ 98 % – Type IIR	98,0 %	Type I Type II Type IIR
Differential pressure (Pa/cm2)	< 40 – Type I < 40 – Type II < 60 – Type IIR	31,8	Type I Type II Type IIR
Splash resistance pressure (kPa)	Not Required – Type I Not Required – Type II ≥ 16 – Type IIR	> 16	Type IIR
Microbial cleanliness (cfu/g)	≤ 30 – Type I ≤ 30 – Type II ≤ 30 – Type IIR	<30	Type I Type II Type IIR
Overall Performance Classification			**Type IIR**

– End of Report –

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

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