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ATTESTATION OF CONFORMITY

Certificate No: MD-371

ICE GRUP PLASTİK ANONİM ŞİRKETİ
Barbaros Mahallesi Mor Sümbül Sokak No:1 Varyap Meridian Business I Blok Kat:8 Ofis:110
Ataşehir / İSTANBUL
Manufacturing Site:
Çerkeşli Osb Mah. 6. İmes 10.Cad No:10 Çerkeşli Köyü Dilovası Kocaeli

The manufacturer's technical documentation (Dated 27.08.2021), 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: ICE PRO MASK, **Model:** MB3
UDI-DI Number: 8683465839MB3L9
Classification: Type II

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 have black, blue and white colour variants.

For more details, refer to the evaluation report provided to the manufacturer, dated 29.11.2021 and number MD-TR-371.

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 **29/11/2021**, will be valid for 1 year from the issue date, without any change in the design and manufacturing process of the product.

İSTANBUL – 29.11.2021

CE

Verify the validity with the QR Code

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

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 number.

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TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 29.11.2021 / MD-TR-371

Manufacturer: ICE GRUP PLASTİK ANONİM ŞİRKETİ

Address: Barbaros Mahallesi Mor Sümbül Sokak No:1 Varyap Meridian Business I Blok Kat:8 Ofis:110 Ataşehir / İSTANBUL

Manufacturing Site: Çerkeşli Osb Mah. 6. İmes 10.Cad No:10 Çerkeşli Köyü Dilovası Kocaeli

SRN: 8683465

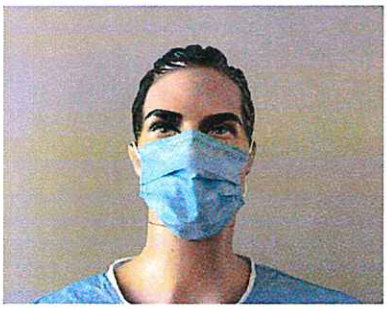
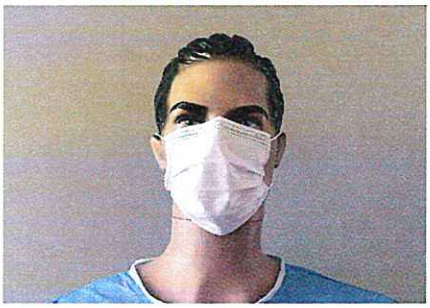
The medical masks (non steril) manufactured by the above manufacturer, are evaluated based on the Annex ZA of harmonised standard EN 14683+AC:2019 and the General Safety and Performance Requirements of EU 2017/745, Medical Device Regulation for Class I products upon the manufacturer request on a voluntary base.

Product Description: 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 have black, blue and white colour variants.

Trademark: ICE PRO MASK **Model:** MB3

UDI - DI: 8683465839MB3L9

Sample Photos


As a third party evaluation, the technical file and other official documentation provided by the manufacturer is evaluated and the samples taken from the manufacturing site during the assessment visit conducted by Universal Certification on 03/08/2021 are tested according to the test requirements referred in Annex ZA of the EN 14683+AC:2019 standard.

See EN ISO/IEC 17025 Accredited Laboratory Test Reports,

Annex I: Test report by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş. dated 01.11.2021 with report number 21032060-Ing.

Annex II: Test report by TUBITAK (The Scientific and Technological Research Council of Turkey) Genetic Engineering and Biotechnology Institute dated 19.11.2021 with report number 16563500-125.05-150/7888.

This report or the issued certificate, in case the report is positive, does not take over or change the sole reponsibility of the manufacturer covered under EU 2017/745 Medical Device Regulation. The manufacturer shall continue to fulfil all responsibilities for Class I products under EU 2017/745 Medical Device Regulation.

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The results of the evaluation are as follows;

A- Review of the technical file, Marking and Information Requirements

In the evaluation of the technical and other official documentation the following information was obtained;

The manufacturer follows the requirements of the EU 2017/745 to establish its technical documentation on the mentioned product. The applicant is a registered manufacturer on the UDI system with the SRN number 8683465. The product is registered in the UDI system with UDI-DI number 8683465839MB3L9.

The manufacturer established a quality management system including a risk management, identification of applicable general safety and performance requirements, strategy for regulatory compliance, product realisation and management of modifications in the device. The management system established is certified based on ISO 13485 standard.

The marking and the information supplied for the consumers are evaluated based on the Annex I Section 23 of the EU 2017/745 regulation and also based on EN 14683+AC:2019 Clause 6. The product package bears the necessary labelling and information necessary for users. The information for use is delivered to the users as printed on the cardboard box. The manufacturer, model of the product, UDI-DI identification, the lot number of the product, shelf life, storage conditions, warnings, limitations, controls before use, the intended use of the product, disposal method are given within this information.

The manufacturer has employed a person in charge responsible for regulatory compliance Me** En*** according to Article 15 of the regulation.

The manufacturer is using the harmonised standard EN 14683+AC:2019 for the product and according to the Article 8 of MDR, the manufacturer claims the fulfilment of requirements relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up ('PMCF').

B- Product Test Results

The tests referenced in Annex ZA are conducted on the samples taken from the manufacturing site and the results are evaluated below. More information can be gathered on tests from the referred test report;

1. **Biocompatibility (Annex II)**

   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. In addition to the manufacturer's declaration on biocompatibility, the samples are tested for irritation according to EN 10993-10:2010 standard and found to have no irritation affect.

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;

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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 II**.

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 **0** For this test result the samples complies the requirement for all performance classes (Type I, Type II and Type IIR).

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 **34,8** 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 32 samples tested were able to provide Type IIR performances as 16kPa resistance.

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C- Summary and Conclusion

Evaluation	Requirement	Result	Classification
Biocompatibility Irritation	Not Irritant	Not Irritant	-
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	34,8	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	0	Type I Type II Type IIR
Overall Performance Classification			**Type II**

– End of Report –

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