DISPOSABLE MASK

PODIMA MEDİKAL

Product Name	2000R
Category	CATEGORY I
N° Certificate	MDD-250
Date of Certificate	04.09.2020-03.09.2021

Digitally signed by Bolea Petru
Date: 2021.09.15 08:50:28 EEST
Reason: MoldSign Signature
Location: Moldova

PRODUCT INFORMATION

Color	: Blue
Packaging	: Single pack of 50 pcs.
Sizes	: Standard
Material	: 80 Gr / m²
Classification	: Standard
Product Type	: Disposable Mask
Model Definition	: 3-Layer Disposable Face Mask

DESCRIPTION FACE MASK

Disposable 3-Layer Surgical Face Mask is produced in a hygienic environment. It is suitable for daily use with its high quality. It does not irritate the skin, it is comfortable to use with the softness of the ear rings and easy breathability.

IDENTIFICATION

EN 14683:2019+AC:2019 Medical Face Masks

ISO 9001: 2015	Quality Management System
ISO 10002: 2018	Customer Satisfaction Management System
ISO 13485: 2016	Medical Devices Management System
ISO 14001: 2015	Environment Management System
ISO 45000: 2018	Occupational and Safety Management System

FDA

WARNINGS

This is an indicative guide only. It must not be used as the only method for selecting the protective garment. Before using any protective clothing. The user must have read and understood all the instructions for use of the product. It is necessary to observe the legislation in force in each individual country. The selection of the most appropriate PPE or accessory depends on the particular situation and should only be made by a competent person who is aware of the specific working conditions and the limitations of PPE and accessories. It is the employer's responsibility to define the suitability of these products for the intended use. This information is subject to review at any time.

PODIMA MEDIKAL VE TEKSTIL SAN.TIC. LTD. STI.
Y.DUDULLU MAH. BAYRAK CAD. NO:30 D:130
UMRANIYE / ISTANBUL 34775

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PACKAGING SIZE

Width*Depth*Height

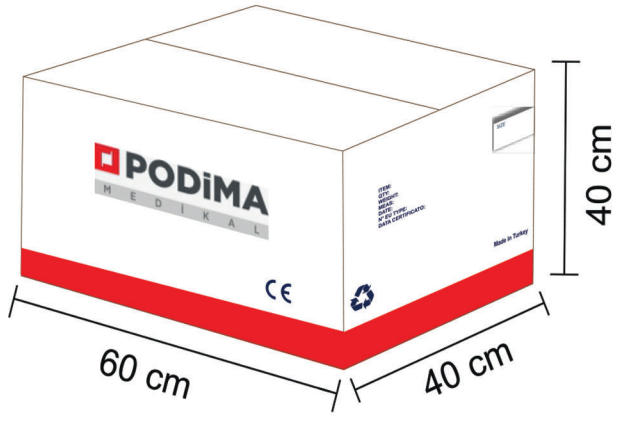
1) Carton Size **60*40*40 cm**

2) Total Pallet Size **120*80*255 cm** (24 cartons in 1 pallet)

1 Container : 852 CTN (Without pallets)
1 Container : 768 CTN in 32 Pallets

- 50 boxes of mask in a single pack

1



2

PODİMA MEDİKAL

PODIMA MEDIKAL VE TEKSTIL SAN.TIC. LTD. STI.
Y.DUDULLU MAH. BAYRAK CAD. NO:30 D:130
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PODIMA

MEDİKAL

Direction for use:

1. Be sure to wash your hands before putting on the mask
2. Open the package and take the mask out. Check that the mask is in good condition. Grasp the mask by the sides and pull it apart. Touch the inner surface while doing this.
3. Fix the mask behind the ears.
4. Position the mask so that it fits correctly.
5. Place your fingers on the nose clip and while moving your fingertips along the nose clip, press until it is shaped into a bridge shape to ensure that the mask is worn properly

How to remove the mask:

When removing the mask do so by only touching the elastic around the ears.
Don’t pull the mask off by the front of the mask.
Discard the mask immediately in a closed bin or a designated bin.
Wash your hands with soap and water and/or disinfect them.

UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-250

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 for

PODİMA BİLİŞİM PAZARLAMA SANAYİ VE TİCARET LİMİTED ŞİRKETİ

İbrahim Ağa Sokak No:14 D.7 Bostancı Kadiköy ISTANBUL / TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name : SUVICOM
Model : 2000R
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 04/09/2020 and valid until 03/09/2021 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 –04/09/2020

CE

Verify the validity with the QR Code

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
General Manager

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.

UNIVERSAL
CERTIFICATION

TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 04.09.2020 / 09-2020-T0359

PODİMA BİLİŞİM PAZARLAMA SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Adress: İbrahim Ağa Sokak No:14 D.7 Bostancı Kadiköy 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: SUVICOM **Model:** 2000R

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 16/07/2020, 20022905 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.

The results of the evaluation are as follows;

UNIVERSAL CERTIFICATION

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

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 **98,4%**. According to this result, the bacteria filtration efficiency performance of the masks is classifified as **Tip 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 **8** 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 **34,2** 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	98,4 %	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	8	Type I Type II Type IIR
Overall Performance Classification			**Type IIR**

– End of Report –

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

EU DECLARATION OF CONFORMITY

MANUFACTURER

PODİMA BİLİŞİM PAZARLAMA SANAYİ VE TİCARET LİMİTED ŞİRKETİ
İbrahim Ağa Sokak No:14 D.7 Bostancı Kadiköy 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 : SUVİCOM
Model : 2000R
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

MARKİNG, LABELLİNG

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.

PODİMA BİLİŞİM PAZ.
SAN. VE TİC. LTD. ŞTİ.

General Manager
Istanbul 04/09/2020

CE

LATEX FREE
DECLARATION OF CONFORMITY

TO WHOM IT MAY CONCERN

We **PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.** hereby confirm that the products below are not made with latex.

MANUFACTURER:	**PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.** *YUKARI DUDULLU MAH. BAYRAK CAD. NO: 30 / 130 ÜMRANİYE 34775 İSTANBUL / TURKEY*
DESCRIPTION:	**DISPOSABLE MASK – TYPE IIR**
SPECIFIATION:	**STERILE AND NON-STERILE**
ITEM NUMBERS:	**2000R**
TRADE MARK:	SUVICOM

APPROVED

Issue Date: 06.04.2021

Sign - Stamp

PODİMA MEDİKAL
VE TEKSTİL SAN. TİC. LTD. ŞTİ.
Yukarı Dudullu Mah. Bayrak Cad. No: 30 D: 130
Ümraniye / İSTANBUL Tic. Sic. No: 889545 - 0
Sarıgazi V.D.: 730 037 5548

www.podimamedikal.com

info@podimamedikal.com

SUVICOM face mask

TEK KULLANIMLIK YÜZ MASKESİ

3 katmanlı | ekstra esnek lastik

Type IIR - Meltblown
EN 14683:2019+AC:2019

50 PCS

CE

SUVICOM face mask

SINGLE USE FACE MASK

3 layer | extra flexible tire

Type IIR - Meltblown
EN 14683:2019+AC:2019

50 PCS

SUVICOM face mask

TEK KULLANIMLIK YÜZ MASKESİ

3 katmanlı | ekstra esnek lastik

CE LOT 202000010

50 ADET / PCS

06.2021 06.2026

8 681282 400003

Type IIR - Meltblown
EN 14683:2019+AC:2019

Podima Bilişim Paz. San. ve Tic. Ltd.
Yukarı Dudullu, Bayrak Cd. No:30 Kat:17
No:130 Dudullu OSB 34775
Ümraniye / İstanbul

CE

SUVICOM face mask

TEK KULLANIMLIK YÜZ MASKESİ

3 katmanlı | ekstra esnek lastik

Type IIR - Meltblown
EN 14683:2019+AC:2019

50 ADET

SUVICOM face mask

TEK KULLANIMLIK YÜZ MASKESİ

3 katmanlı | ekstra esnek lastik

Burun Telli
Nose Wire

Tek kullanımlık lastikli
Single use

Ekstra esnek lastik
Extra flexible tire

Hijyenik ortamda üretilmiştir.
Produced under hygienic conditions

CE

50 ADET