(3) mediroc

TECHNICAL DATASHEET



FACE MASK

3-PLY EARLOOP



GENERAL INFORMATION

MANUFACTURER

Name: STL Teknoloji Ltd. Şti.

Add: Catalcesme Mah. Resadiye Cad. 186 Sok. No: 18 Alemdag, Cekmeköy, İstanbul/TURKEY

Authorized Representative: Mediroc Tech LTD.

CONFORMITY ASSESSMENT PROCEDURE

According to Regulation (EU) 2017/745 Article 52, the manufacturer follows the conformity assessment procedure relating to the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III.

NOTIFIED BODY

No involvement of a Notified Body is needed for this



PRODUCT INFORMATION

INTENDED USE

- Low-risk clinical applications that do not involve blood-borne pathogens or bodily fluids
- Enhancing infection control
- Preventing the risk of cross-contamination

DESCRIPTION

Rectangular face masks with a shapeable nose piece and two earloops present, one on each side, in order to hold mask in place.

Trade Mark: Mediroc

Model: STL3PLY

This product is **Type II** mask according to European Standard EU: BS EN 14683:2019

MATERIAL

Outside Layer: Spunbond Polypropylene – SBPP (White) Middle Layer: Meltblown Polypropylene – MBPP (White) Inner Layer: Spunbond Polypropylene – SBPP (White)

Nose piece: Plastic covered iron

Elastic Band: Polyester

Not formulated with Natural Rubber Latex (Latex Free)

Not formulated with DEHP Fiberglass Free Product

MASK DIMENSIONS

Length: 175mm Width 95mm Length of ear loop: 170mm Length of nose piece: 90mm

MANUFACTURING

This mask is made in Turkey.

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REGULATION & TESTING INFORMATION

REGULATORY INFORMATION

Product CE marked as per 93/42/EEC Directive on Medical Devices.

Class 1 Medical Device - Type II - Non-Sterile

TEST METHODS

Bacterial Filtration Efficiency (BFE)

When tested in accordance with Annex B of EN 14683, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1 of EN 14683.

Breathability

When tested in accordance with Annex C of EN 14683, the differential pressure of the medical face mask shall conform to the value given in relevant type in Table 1 of EN 14683.

Microbial cleanliness (Bioburden)

The bioburden of the medical face mask shall be ≤ 30 cfu/g tested. The number of masks that shall be tested is minimum 5 of the same batch/lot.

The number of masks that shall be tested is minimum 5 of the same batch/lot.

Differential Pressure

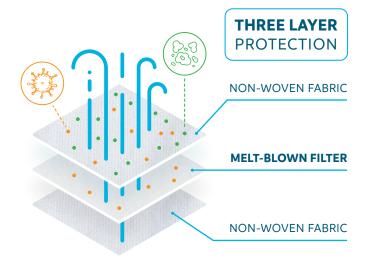
The differential pressure of the medical face mask shall be \leq 40 cfu/g tested. The number of masks that shall be tested is minimum 5 of the same batch/lot.

TEST	TYPEI	TYPE II	TYPE IIR
Bacterial Filtiration Efficiency(BFE), (%)	≽95	≽98	≽98
Differantial Pressure (Pa/cm2)	<40	<40	<60
Splash Resistance Pressure (kPa)	Not Required	Not Required	<u>≽</u> 16,0
Microbial Cleanliness (cfu/g)	≤ 30	≤ 30	≤30

Table – Performance Requirements for Medical Face Masks

STERILIZATION

This mask is non-sterile



STORAGE

Store in a dry and cool place, away from intense sources of heat. Keep the masks as much as practicably possible in their dispenser box. Keep dispenser boxes as much as practicably possible in their shipper box.

PACKING

Shipping case of 1000 units 10 Units are placed within 1 box and 100 boxes are placed within 1 shipping case.

Box dimensions: 220x105x25mm Box material: 350gr Paper

Shipping case dimensions: 640x460x230mm

Shipping case material: Carton

SHELF LIFE

The shelf-life is 3 years after production. The uninterrupted use duration of the device is usually less than 8 hours.

BARCODE



VISUALS



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Disposable Medical **FACE MASK**

FACE MASK

3-PLY EARLOOP

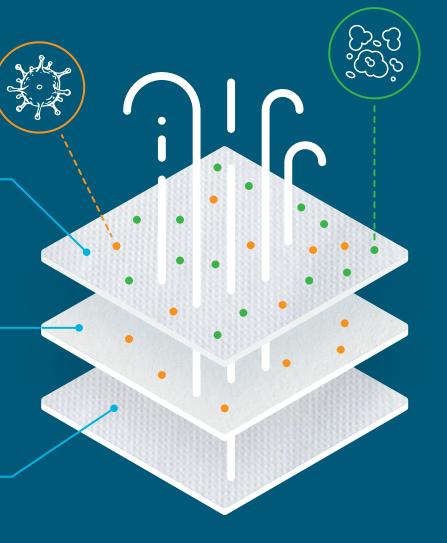


THREE LAYER PROTECTION

Non-Woven Fabric

Melt-Blown Filter

Non-Woven Fabric





TEST REPORT

Class 1 Medical Device

Standard EU: BS EN 14683:2019



ANALYSIS REPORT

Report No. : 2011194E-R1 Report Date : 02/06/2020

Applicant : STL TEKNOLOJİLTD. ŞTİ.

Address : Alemdağ, Çatalmeşe Mah. Reşadiye Cad, 186. Sk. No:18

Çekmeköy/ İstanbul/ Turkey

Sample : Disposable Medical Face Mask

Sample Package : Carton box
Sample Amount : 100 adet

Sampling Point : Sampling Date : Sample Lot No. : -

Sample Carrying Conditions / Preservation

Technique

Production Date : 05/2020
Packing Date : Expire Date : 2023

Producer Company : STL Teknoloji Ltd. Şti.
Sample Receiving Time : 21/05/2020 10:30:00
Analysis Beginning Time : 21/05/2020 10:45:00

Analysis Completion Time : 29/05/2020

Following analysis results were obtained from the specimen which was delivered by cargo to Çevre Laboratory;

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
Differential Pressure								
DP - 1	Pa/cm²	16,73	< 40	< 40	< 60	97	EN 14683 - Annex	C 122, 123, 126
DP - 2	Pa/cm²	19,02	< 40	< 40	< 60	97	EN 14683 - Annex	с С 122, 123, 126
DP - 3	Pa/cm²	16,52	< 40	< 40	< 60	97	EN 14683 - Annex	C 122, 123, 126
DP - 4	Pa/cm²	17,1	< 40	< 40	< 60	97	EN 14683 - Annex	с С 122, 123, 126
DP - 5	Pa/cm²	15,92	< 40	< 40	< 60	97	EN 14683 - Annex	с С 122, 123, 126
Bacterial Filtration Efficiency								
BFE - 1	%	99,6	≥95	≥98	≥98	97	EN 14683 - Annex	к В 122, 124, 129
BFE - 2	%	99,6	≥95	≥98	≥98	97	EN 14683 - Annex	к В 122, 124, 129
BFE - 3	%	99,6	≥95	≥98	≥98	97	EN 14683 - Annex	к В 122, 124, 129
BFE - 4	%	99,9	≥95	≥98	≥98	97	EN 14683 - Annex	к В 122, 124, 129

Merve BİRAH Assistant Laboratory Responsible of Microbiology Laboratory Approved by 02/06/2020 Ömer Yasin BALIK Laboratory Manager



ANALYSIS REPORT

Report No.: 2011194E-R1 Report Date : 02/06/2020

Following analysis results were obtained from the specimen which was delivered by cargo to Çevre Laboratory;

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
BFE - 5	%	99,6	≥95	≥98	≥98	97	EN 14683 - Annex E	3 122, 124, 129
Mean Positive Control Count	cfu	2395	-	-	-	-	EN 14683 - Annex E	3
Negative Control Count	cfu	<1	-	-	-	-	EN 14683 - Annex E	3
Mean Particle Size (MPS)	μm	2,9	=	=	=	=	EN 14683 - Annex E	3
Microbial Limit - Bioburden								
Bioburden - 1	cfu/g	22	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 2	cfu/g	16	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 3	cfu/g	19	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 4	cfu/g	16	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 5	cfu/g	22	≤30	≤30	≤30	97	ISO 11737-1	120, 131

Source of Limit Ranges

:97 Medikal Yüz Maskelerinin Test Metodları ve Performans Gereksinimleri (EN 14683)

A: Acceptable NA: Not Acceptable MU: Measurement Uncertainty

Method EN: European Standard

ISO: International Organization for Standardization

Information 120 : Bioburden : Aerobic Bacteria and Mold-Yeast

Pozitive Controls : Bacillus atrophaeus

Extract Fluid: Peptone, Tween with Sodium Chloride

Extract Fluid Volume: 300 mL Plating Method : Membrane Filtration

Agar Medium: Tryptic Soy Agar for Aerobic Bacteria Count and Sabouraud Dextrose Agar with Chloramphenicol for Mold

and Yeast Count

Recovery Efficiency: Repetitive Rinse Method

Aerobic Bacteria: Plates are incubatede 3 days at 30-35°C, then enumerated. Yeast - Mould : Plates are incubatede 5-7 days at 20-25°C, then enumerated.

122 Conditioning Parameters: 85± 5 relative humidity and 21± 5 °C de minimum 4 hours

123 : Flow rate during testing : 8 L/dk 124 : Flow rate during testing : 28.3 L/dk

126 : The mask analyzed according to the results of Differential Pressure provides EN 14683 Table 1. Type I, Type II and Type IIR limits.

: The mask analyzed according to the results of Bacterial Filtration Efficiency (BFE) provides EN 14683 Table 1. Type I, Type II and Type IIR limits.

131 : The mask analyzed according to the results of Microbial Limit - Bioburden provides the EN 14683 Table 1. Type I, Type II and Type IIR limits.

R1 : This report supersedes 29/05/2020 date 2011194E number of report which is invalid.

Merve BİRAH **Assistant Laboratory Responsible of Microbiology Laboratory**

Approved by 02/06/2020 Ömer Yasin BALIK **Laboratory Manager**



ANALYSIS REPORT

Report No. : 2011194E-R1 Report Date : 02/06/2020

Note

- When request, the conformit assessment is carried out in accordance with the legal regulations and standards or the decision rules which are agreed with the customer.
 Descriptive information about the samples / sampling in the analysis report has been declared by the customer. Our laboratory is not responsible for the legal losses.
 Analysis report covers samples/sampling that comes to the laboratory.
 This report and results don't not be copied and printed partially or completely without permission of Cevre Industrial Analysis Laboratory for any commercial and extending surrecess. advertising purposes.
 5. This report shall not be used official purposes related to Environmental Regulations.
 6. The test report without sign is not valid.

End of Report

Merve BİRAH **Assistant Laboratory Responsible of Microbiology Laboratory**

Approved by 02/06/2020 Ömer Yasin BALIK **Laboratory Manager**



EU DECLARATION OF CONFORMITY & CERTIFICATION

EU DECLERATION OF CONFORMITY



Mediroc Disposable Medical Face Mask

Name and address of manufacturer : STL TEKNOLOJİ LTD. ŞTİ.

Alemdağ, Çatalçeşme Mah. Reşadiye Cad. 186. Sok. No:18

Çekmeköy/İstanbul/Turkey

Product Name : Disposable Medical Face Mask

Brand Name : (4) mediroc

Product Types : Type II, Non-Sterile
Authorized Representative : Mediroc Tech Ltd.

This declaration confirms that the product meets the essential requirements of following directive(s) and standart(s). The conformity was based on;

Applied Directive(s) : Medical Devices Directive 93/42/EEC as amended according to

the Directive 2007/47/EC

Applied Standard(s) : EN 14683:2019 Medical Face Masks - Requiremenst and test methods

International Standards : ISO 13485:2016 / ISO 9001:2015(QMS)

The declaration has been carried out in accordance with individual rules and conditions. Evaluation has been carried out in accordance with:

Test Report(s) No : 20011194E-R1

Test Conducted by : Cevre Industrial Analysis Laboratory

Test Lab. Adress : Merkez Mahallesi Tatlıponar Sokak No: 13 Mart Plaza Kat: 2/A

Kağıthane/İstanbul

Issue Date : 02/06/2020

Revision Date/No : -

* The undersinged herewith declarer that the above-mentioned product(s) meet the provisions of the following EC Council Directives and harmonized standards, All supporting documentations are retained under the premises of the manufacturer.

İstanbul/Turkey General Manager 05.06.2020

Çatalme Alemda Sarıgazi

STLTEKNOLOJI LTD. STI.

Çatalmeşe Mah. Reşaliye Cad. 186 Sk. No: 18
Alemdağ - Çekmekey İlstanbul TÜRKİYE
Sarıgazi V.D.:773 030 1141 ks. Sic. No: 575043
Mersis No: 07 3838 16100010
http://benceiyi.com-info@benceiyi.com
Tel.: 02163145521 Fax: 02163145523



This Certificate has been awarded to

STL TEKNOLOJİ LİMİTED ŞİRKETİ

ÇATALMEŞE MAH. REŞADİYE CAD. 186. SOK. NO:18 ÇEKMEKÖY / İSTANBUL / TÜRKİYE

In recognition of the organization's Managements System which complies with

EN 14683:2019+AC:2019

The scope of activities covered by this certificate is defined below

MANUFACTURE, SALES AND EXPORTS OF TEXTILE PRODUCTS, MEDICAL PROTECTIVE CLOTHING, MASK, PROTECTIVE OVERALLS, BONNET, GLOVES, OVERSHOE, APRON, SURGERY APRON FOR PATIENTS AND DOCTOR, STRETCHER COVER, DEAD BODY BAG, COLONOSCOPY SHORTS, PATIENT SHORTS, DISINFECTANT LIQUIDS, ANTIBACTERIAL SOAP AND LIQUIDS, SURFACE AND SKIN CLEANING MATERIALS, FACE PROTECTOR VISORS, SUITCASE

TEKSTİL ÜRÜNLERİ, MEDİKAL KORUYUCU KIYAFET, MASKE, KORUYUCU TULUM, BONE, ELDİVEN, GALOŞ, ÖNLÜK, HASTA VE DOKTOR İÇİN AMELİYAT ÖNLÜĞÜ, SEDYE ÖRTÜSÜ, CESET TORBASI, KOLONOSKOPİ ŞORTU, HASTA ŞORTU, DEZENKFEKTAN SIVILAR, ANTİBAKTERİYAL SABUN VE SIVILAR, YÜZEY VE CİLT TEMİZLİK MALZEMELERİ, YÜZ KORUYUCU SİPERLİK, VALİZ ÜRETİMİ, SATIŞI VE İHRACATI

Certificate Number: SISTURAC052020104
Date of Issue of Original Certificate: 06.05.2020
Date of Issue of latest certificate: 27.05.2020

Expiry Date: 05.05.2021

SYNDICATE OF INTERNATIONAL SYSTE



Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid.

Corporate office(SIS):- Plot No. 1539, 2nd Floor, Sector-4,Gurgaon-122001, Haryana, India. International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047. Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91-9654721646 Web:- http://www.siscertifications.co.in, www.siscertifications.com The status of this certificate can be verified on "http://www.siscertifications.co.in".





This Certificate has been awarded to

STL TEKNOLOJİ LİMİTED ŞİRKETİ

ÇATALMEŞE MAH. REŞADİYE CAD. 186. SOK. NO:18 ÇEKMEKÖY / İSTANBUL / TÜRKİYE

In recognition of the organization's Management System which complies with

ISO 9001:2015(QMS)

The scope of activities covered by this certificate is defined below

MANUFACTURE, SALES AND EXPORTS OF TEXTILE PRODUCTS, MEDICAL PROTECTIVE CLOTHING, MASK, PROTECTIVE OVERALLS, BONNET, GLOVES, OVERSHOE, APRON, SURGERY APRON FOR PATIENTS AND DOCTOR, STRETCHER COVER, DEAD BODY BAG, COLONOSCOPY SHORTS, PATIENT SHORTS, DISINFECTANT LIQUIDS, ANTIBACTERIAL SOAP AND LIQUIDS, SURFACE AND SKIN CLEANING MATERIALS, FACE PROTECTOR VISORS, SUITCASE

TEKSTİL ÜRÜNLERİ, MEDİKAL KORUYUCU KIYAFET, MASKE, KORUYUCU TULUM, BONE, ELDİVEN, GALOŞ, ÖNLÜK, HASTA VE DOKTOR İÇİN AMELİYAT ÖNLÜĞÜ, SEDYE ÖRTÜSÜ, CESET TORBASI, KOLONOSKOPİ ŞORTU, HASTA ŞORTU, DEZENKFEKTAN SIVILAR, ANTİBAKTERİYAL SABUN VE SIVILAR, YÜZEY VE CİLT TEMİZLİK MALZEMELERİ, YÜZ KORUYUCU SİPERLİK, VALİZ ÜRETİMİ, SATIŞI VE İHRACATI

Certificate Number: SISTURQ0420202085
Date of Issue of Original Certificate: 22.04.2020
Date of Issue of latest certificate: 27.05.2020

Expiry Date: 22.04.2021



Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

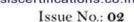
The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid. This is an accredited certificate issued by SIS Certifications Pvt. Ltd. sanctioned for issue by International Accreditation Services, 3060 Saturn Street Suite 100 Brea, California 92821-1732, USA.

Corporate office(SIS):- Plot No. 1539, 2nd Floor, Sector-4, Gurgaon-122001, Haryana, India. International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047. Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91-9654721646 Web:- http://www.siscertifications.co.in, www.siscertifications.com The status of this certificate can be verified on "http://www.siscertifications.co.in".











CE

CE ATTESTATION OF CONFORMITY

Related Directives : MEDICAL DEVICES 93/42/EEC----TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

Class Smif: CLASS 1 / SINIF 1, NON STERILE

Description of Product : MEDICAL MASK TIBBİ MASKE

Manufactured by

STL TEKNOLOJI LİMİTED ŞİRKETİ

ÇATALMEŞE MAH. REŞADİYE CAD. 186. SOK. NO:18 ÇEKMEKÖY / İSTANBUL / TÜRKİYE

Certificate No.: SISTURCE052020705 Issue Date (Original): 06.05.2020 Issue Date(Latest): 26.05.2020

Expiry Date: 05.05.2021

CE

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate is issued under the following conditions:

1.It applies only to the above referenced models of the medical devices.

2.It does not imply that the SIS has performed any surveillance or control of their manufacture.

3. The manufacture is obligated to assure conformity of all in medical devices of the respective model to type assessed by the mean of this certificate.

4.The certificate remains valid until the manufacturing condition, the quality system or relevant legislation are changed.

5. After fulfilling of the relevant EU legislation requirements, the manufacture shall affix to each medical device, of the above referenced models, the CE-marketing according to this example:



Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.



The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid.

Corporate office(SIS):- Plot No. 1539, 2nd Floor, Sector-4, Gurgaon-122001, Haryana, India. International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047. Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91-9654721646 Web:- http://www.siscertifications.co.in, www.siscertifications.com The status of this certificate can be verified on "http://www.siscertifications.co.in".



CERTIFICATE

of Registration



This is to Certify that the

Medical Devices - Quality Management System

of

STL TEKNOLOJİ LİMİTED ŞİRKETİ

ÇATALMEŞE MAH. REŞADİYE CAD. 186. SOK. NO:18 ÇEKMEKÖY / İSTANBUL / TÜRKİYE

has been independently assessed and is compliant with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

MANUFACTURE, SALES AND EXPORTS OF MEDICAL PROTECTIVE CLOTHING, MASK, PROTECTIVE OVERALLS, BONNET, GLOVES, OVERSHOE, APRON, SURGERY APRON FOR PATIENTS AND DOCTOR, STRETCHER COVER, DEAD BODY BAG, COLONOSCOPY SHORTS, PATIENT SHORTS, DISINFECTANT LIQUIDS, ANTIBACTERIAL SOAP AND LIQUIDS, SURFACE AND SKIN CLEANING MATERIALS, FACE SHIELDS

MEDİKAL KORUYUCU KIYAFET, MASKE, KORUYUCU TULUM, BONE, ELDİVEN, GALOŞ, ÖNLÜK, HASTA VE DOKTOR İÇİN AMELİYAT ÖNLÜĞÜ, SEDYE ÖRTÜSÜ, CESET TORBASI, KOLONOSKOPİ ŞORTU, HASTA ŞORTU, DEZENKFEKTAN SIVILAR, ANTİBAKTERİYEL SABUN VE SIVILAR, YÜZEY VE CİLT TEMİZLİK MALZEMELERİ, YÜZ KORUYUCU SİPERLİK ÜRETİMİ, SATIŞI VE İHRACATI

:: Certificate No :: TR52007H

Date of initial registration 22 April 2020

Date of this Certificate 22 May 2020

Surveillance audit on or before 21 April 2021

Recertification Due / Certificate expiry 21 April 2023

This Certificate is property of Staunchly Management & System Services Ltd. and remains valid subject to satisfactory surveillance audits.



Director

STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.

Suite 48, 88-90 Hatton Garden, London, EC1N 8PN.

Phone: +44 345 680 0199

Email: info@staunchlyservices.com Web: www.staunchlyservices.com

SMS/F109A/17/REV02

For precise and updated information concerning the present certificate mail to info@staunchlyservices.com
This Certificate is the property of Staunchly Management & System Services Private Limited and shall be returned immediately when demanded



PACKAGING





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THANK YOU!

