# (3) mediroc

#### TECHNICAL DATASHEET



## KID'S 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 Non-Sterile class I device.



#### **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: STL3PLYKIDS

This product is Type IIR 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: 145mm Width 75mm Length of ear loop: 160mm 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 IIR - 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  $\leq 30$  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.

### Splash Resistance, Synthetic Blood Res. (Splash Resistance, Synthetic Blood Res.)

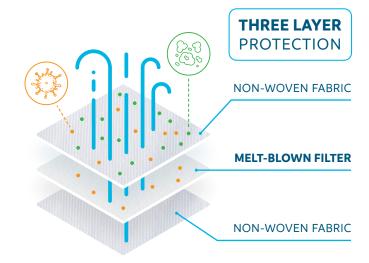
Synthetic Blood Penetration - The Splash Resistance test is one of two synthetic blood resistance tests offered by the Environmental Laboratory to determine a product's ability to act as a barrier against blood-borne pathogens. The test method is applied by splashing a fixed volume of synthetic blood directed at high speed to the center of the mask.

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

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 demision: 210x105x24,5mm Box matarial: 350gr Paper

Shipping case demision: 640x325x500mm

Shipping case matarial: 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** 

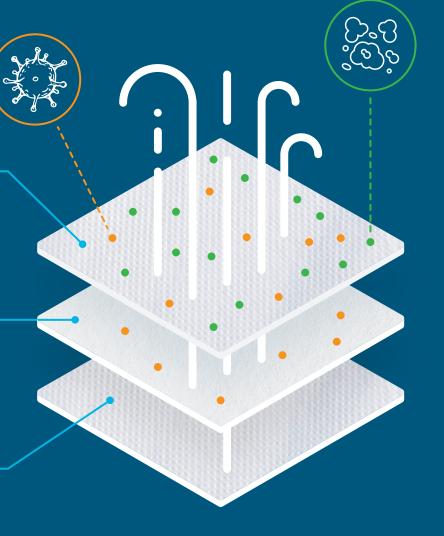


### THREE LAYER PROTECTION

Non-Woven Fabric

**Melt-Blown Filter** 

Non-Woven Fabric





Class 1 Medical Device

Standard EU: BS EN 14683:2019



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



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

 ${\sf ISO:International\ Organization\ for\ Standardization}$ 

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.

129 : 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



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** 



Report No. : 2019969E Report Date : 28/08/2020

Applicant : STL TEKNOLOJİ LTD. ŞTİ.

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

Çekmeköy/İstanbul/Turkey

Sample : Disposable Face Mask Wexta / Model: STL3PLY

Sample Package : Carton box
Sample Amount : 50 pieces

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

Sample Carrying Conditions / Preservation

Technique

Production Date : 07/2020
Packing Date : Expire Date : 2023

Producer Company : STL Teknoloji Ltd. Şti.
Sample Receiving Time : 21/08/2020 12:30:00
Analysis Beginning Time : 21/08/2020 12:45:00

Analysis Completion Time : 27/08/2020

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

Parameters	Unit	Finding	Method	Information
Splash Resistance Pressure				
Splash Resistance Pressure	kPa	16	ISO 22609	122, 142, 146, 147
Number of Masks Analyzed	-	32	-	
Number of Passed Masks Analyzed	-	30	-	
Analyzed Mask Surface	-	Outside	-	
Point of Analysis	-	Midpoint	-	

MU: Measurement Uncertainty

Method ISO: International Organization for Standardization

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

142 : The Splash Resistance Pressure is determined based on the value specified in EN 14683 Table 1. Type IIR.

16 : According to ISO 22609, when 29 or more of the 32 samples tested show "pass" results, an acceptable 4.0% quality limit is met for a single sampling plan. Acceptable 4.0% quality limit is met for normal sampling plan according to analysis results.

Okan PELIT

Laboratory Responsible

Approved by 28/08/2020 Ömer Yasin BALIK Laboratory Manager



Report No. : 2019969E Report Date :28/08/2020

147 : Test Parameters : %60 relative humidity and 26 °C□

Note

- 1. 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.

  2. 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.

  3. Analysis report covers samples/sampling that comes to the laboratory.

  4. 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 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

Okan PELIT **Laboratory Responsible** 

Approved by 28/08/2020 Ömer Yasin BALIK **Laboratory Manager** 



Job No./Report No TR1809940

Date:26 October 2020 Page 1 of 7

#### STL TEKSNOLOJİ LIMITED ŞIRKETI

ÇATALÇEŞME MAH REŞADİYE CAD 186. SOK NO 18 ALEMDAĞ ÇEKMEKÖY

TEL: 05446993444

#### To the attention of Musab Erkus

The following sample(s) was (were) submitted and identified by/on behalf of the client as:

Sample No.	Sample Description
Α	Face Mask – Koruyucu Yüz Maskesi

Client's reference No. TR 1809940

Colour White

Manufacturer STL TEKNOLOJI LİMİTED ŞİRKETİ HOLLAND-ITALY-FRANCE-SPAIN Country of Destination

Sample Receiving Date 08 October 2020

**Test Performing Period** 08 October 2020~26 October 2020

**Overall Conclusion PASS** 

**Test Results** Please refer to the next page(s).

**Performed Test Summary:** Selected test(s) as requested by client against Client's performance standard.

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Unless otherwise requested SGS applies shared risk decision rule

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Unless otherwise requested the results shown in this test report refer only to the sample(s) tested. Unless further specified in an individual contract the sample(s) retention time is 30



Job No./Report No TR1809940

Date:26 October 2020 Page 2 of 7

Test Parameters	Result
Physical tests	<u>A</u>
Breathability (Differential Pressure)	M

Test Parameters	Result
Microbiological tests	<u>A</u>
Bacterial Filtration Efficiency (BFE)	M
Bioburden	M

Remarks	M = Meets client's requirement
	F = Does not meet client's requirement
	I = Inconclusive
	* = No specified requirement
Notes:	Conclusions on meet/fail are based on the test result from the actual sampling of the received sample(s).
	Residual sample can be returned to client if requested.

The test results relate to the tested items only.

Test reports without SGS seal and authorised signatures are invalid.

Issued in Istanbul Signed for and on behalf of

SGS Supervise Gözetme Etüd Kontrol Servisleri A.Ş.

Mert Kurtuluş **Customer Services Supervisor**  Bora Şirinbilek

Hardline & CPCH Testing Services Manager



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In this Test Report tests marked (1) are included in the TURKAK Accreditation Scope of this Laboratory.



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Date:26 October 2020

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#### **BACTERIAL FILTRATION EFFICIENCY (BFE) TEST**

REFERENCE-TEST METHOD	EN 14683:2019 / ASTM F2101-19
Test Method	BFE test is performed to determine the bacterial filtration efficiency of the samples. The Staphylococcus aureus suspension is passed over the sample at a constant flow rate and air pressure by means of a nebulizer. This bacterial aerosol is collected with six-stage sampler (Andersen Sampler). The bacterial aerosol to which the sample is exposed is 1.7-2.7 x 10 <sup>3</sup> cfu, with a mean particle size 3.0 ± 0.3 microns
Analysis Number	5

TEST RESULTS						
Conditioning Parameters	(21 ±5) C°, %	(85±5), 4 hours	3			
Test Side of Samples	Inner side (Fa	acing side)				
Test Area of Sample	~42cm <sup>2</sup>					
Test Flow Rate	28,3 l/min					
Positive Control Average	~2,5x10 3 cfu					
Negative Control Average	<1 cfu					
Total Plate Count for Each	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	
Stage (cfu)						
Stage 1	0	1	1	0	0	
Stage 2	0	0	0	1	0	
Stage 3	0	1	0	1	0	
Stage 4	1	2	1	2	1	
Stage 5	22	33	34	44	23	
Stage 6	26	38	29	51	22	
Total Cfu	49	75	65	99	46	
% BFE	98,3 98,1 98,7 99,5 98,4					
Average % BFE	98,6%					
Conformity	NS	NS	NS	NS	NS	
Acceptance Criteria	≥95	≥95	≥95	≥95	≥95	

S: Suitable, NS: Non-Suitable, NA: Not Applicable

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#### **BREATHABILITY (DIFFERENTIAL PRESSURE) TEST**

REFERENCE-TEST METHOD	EN 14683:2019
Test Method	Differential pressure test is performed to test the breathability by measuring the pressure on both sides of the sample by means of a manometer at constant flow rate.
Analysis Number	5

TEST RESULTS						
Mask Description		Face Mask				
Number and General L	ocation of the Areas	5 pieces-Middle part				
of the Mask						
Conditioning Parameter	ers	(21 ±5) C°, % (85±5), 4 hours				
Test Flow Rate		8 l/min				
Sample	Result (Pa/cm <sup>2</sup> )	Conformity	Acceptance Criteria			
1	18,36	S	<40			
2	18,36	S	<40			
3	18,36	S	<40			
4	16,32	S <40				
5	20,40	S	<40			

S: Suitable, NS: Non-Suitable, NA: Not Applicable

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Date:26 October 2020 Page 5 of 7

#### **BIOBURDEN TEST**

Test Method	TS EN ISO 11737-1 Orbital Shaking-Membrane Filtration Method
Analysis Number	5

TEST RESULTS			
Analysis	Results (cfu/g)	Conformity	Acceptance Criteria
Total Aerobic Mesophilic	9		
<b>Bacteria</b> (30-35 °C / 3-7 days)		-	-
Total Mold-Yeast	0		
(20-25 °C / 5-7 days)		-	-
Total number of	9		
microorganism		S	≤30 cfu/g

TEST RESULTS			
Analysis	Results (cfu/g)	Conformity	Acceptance Criteria
Total Aerobic Mesophilic	7		
<b>Bacteria</b> (30-35 °C / 3-7 days)		-	-
Total Mold-Yeast	0		
(20-25 °C / 5-7 days)		-	-
Total number of	7		
microorganism		S	≤30 cfu/g

TEST RESULTS			
Analysis	Results (cfu/g)	Conformity	Acceptance Criteria
Total Aerobic Mesophilic	6		
<b>Bacteria</b> (30-35 °C / 3-7 days)		-	-
Total Mold-Yeast	0		
(20-25 °C / 5-7 days)		-	-
Total number of	6		
microorganism		S	≤30 cfu/g

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TEST RESULTS			
Analysis	Results (cfu/g)	Conformity	Acceptance Criteria
Total Aerobic Mesophilic	7		
<b>Bacteria</b> (30-35 °C / 3-7 days)		-	-
Total Mold-Yeast	0		
(20-25 °C / 5-7 days)		-	-
Total number of	7		
microorganism		S	≤30 cfu/g

TEST RESULTS			
Analysis	Results (cfu/g)	Conformity	Acceptance Criteria
Total Aerobic Mesophilic	6		
<b>Bacteria</b> (30-35 °C / 3-7 days)		-	-
Total Mold-Yeast	0		
(20-25 °C / 5-7 days)		-	-
Total number of	6		
microorganism		S	≤30 cfu/g

CONTROL TESTS			
Negative Control	No growth detected	S	No growth should be detected

S: Suitable, NS: Non-Suitable, Cfu:Colony-forming unit, SIP: Sample item portion, TNTC:Too numerous

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Unless otherwise requested SGS applies shared risk decision rule

Unless otherwise requested SGS applies shared risk decision rule
Unless otherwise requested the results shown in this test report refer only to the sample(s) tested. Unless further specified in an individual contract the sample(s) retention time is 30

<sup>\*\*</sup>These tests have been performed as subcontracted.



Job No./Report No TR1809940

Date:26 October 2020 Page 7 of 7



**End of Test Report** 

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Unless otherwise requested SGS applies shared risk decision rule
Unless otherwise requested the results shown in this test report refer only to the sample(s) tested. Unless further specified in an individual contract the sample(s) retention time is 30



## EU DECLARATION OF CONFORMITY & CERTIFICATION

#### **EU DECLARATION 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 R, 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

05.06.2020

General Manager

STLTEKNOLOJI LTD. STİ.

Çatalmeşe Mah. Reşatiye Cad. 186 Sk. No: 18
Alemdeğ - Çekmekey İlstanbul - TÜRKİYE
Sarıgazi V.D.:773 030 ilk illər. Sic. No: 575043
Mersis No: 07 3838 if 6100010
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".





ACCREDITED

Management Systems

Certification Body



This Certificate has been awarded to

## STL TEKNOLOJİ LİMİTED ŞİRKETİ

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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

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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.

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Issue No.: 02



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#### 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 LIMITED 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.

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## 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

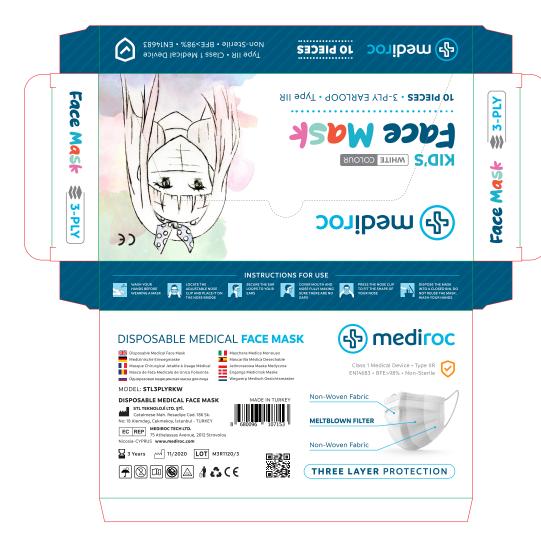
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For precise and updated information concerning the present certificate mail to info@staunchlyservices.com
This Certificate is the property of Staunchly Management & System Services Private Limited and shall be returned immediately when demanded



**PACKAGING** 





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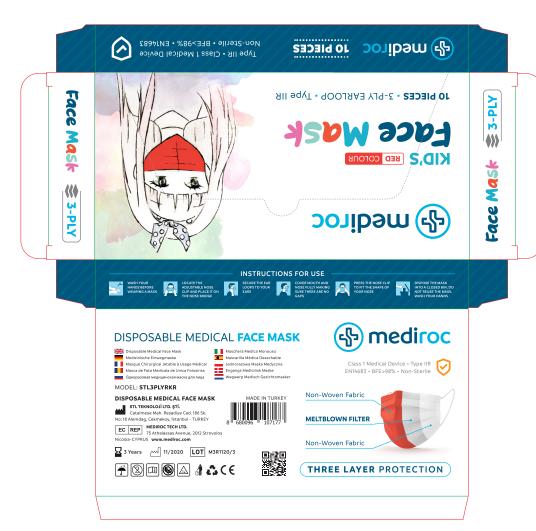
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