



mediroc



# KID'S FACE MASK

## 3-PLY EARLOOP



### GENERAL INFORMATION

#### MANUFACTURER

Name: STL Teknoloji Ltd. Şti.

Add: Catalcesme Mah. Resadiye Cad. 186 Sok. No: 1 8  
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 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

#### DEMISIONS

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

#### MANUFACTURING

This mask is made in Turkey.



## 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  $\leq 30$  cfu/g tested. The number of masks that shall be tested is minimum 5 of the same batch/lot.

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#### Differential Pressure

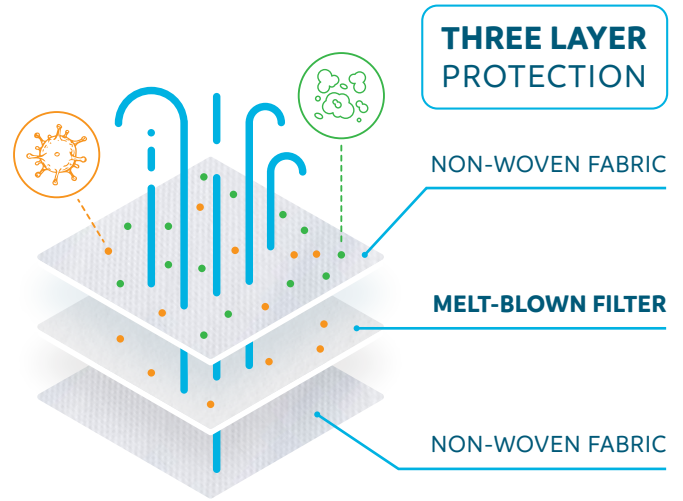
The differential pressure of the medical face mask shall be  $\leq 40$  cfu/g tested. The number of masks that shall be tested is minimum 5 of the same batch/lot.

TEST	TYPE I	TYPE II	TYPE IIR
Bacterial Filtration Efficiency(BFE), (%)	$\geq 95$	$\geq 98$	$\geq 98$
Differential Pressure (Pa/cm <sup>2</sup> )	<40	<40	<60
Splash Resistance Pressure (kPa)	Not Required	Not Required	$\geq 16,0$
Microbial Cleanliness (cfu/g)	$\leq 30$	$\leq 30$	$\leq 30$

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: 210x105x24,5mm

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





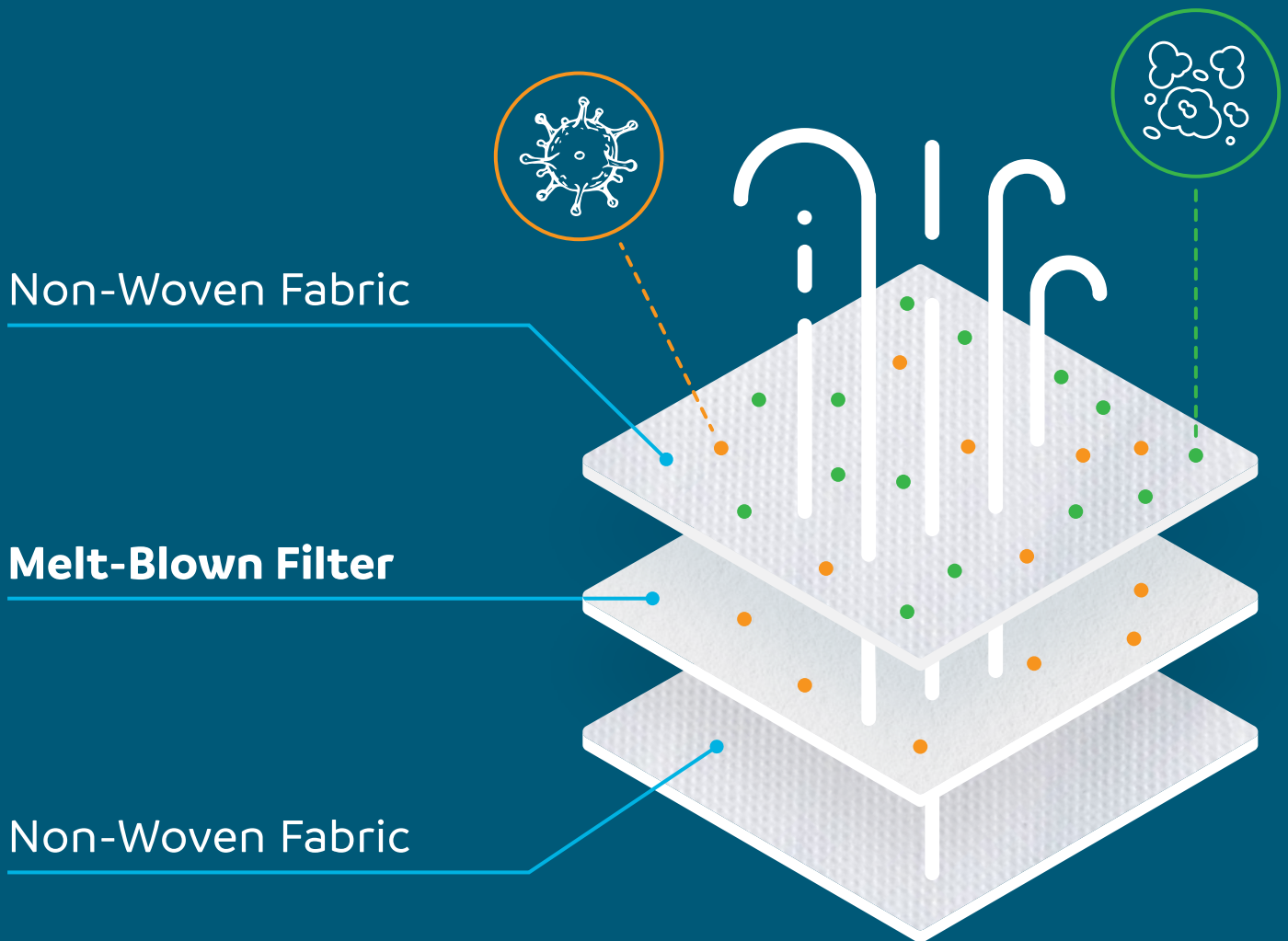
Disposable Medical  
**KID'S FACE MASK**

# DISPOSABLE MEDICAL FACE MASK

3-PLY EARLOOP



## THREE LAYER PROTECTION





# 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 TEKNOLOJİ LTD. 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/cm <sup>2</sup>	16,73	< 40	< 40	< 60	97	EN 14683 - Annex C 122, 123, 126	
DP - 2	Pa/cm <sup>2</sup>	19,02	< 40	< 40	< 60	97	EN 14683 - Annex C 122, 123, 126	
DP - 3	Pa/cm <sup>2</sup>	16,52	< 40	< 40	< 60	97	EN 14683 - Annex C 122, 123, 126	
DP - 4	Pa/cm <sup>2</sup>	17,1	< 40	< 40	< 60	97	EN 14683 - Annex C 122, 123, 126	
DP - 5	Pa/cm <sup>2</sup>	15,92	< 40	< 40	< 60	97	EN 14683 - Annex C 122, 123, 126	
Bacterial Filtration Efficiency								
BFE - 1	%	99,6	≥95	≥98	≥98	97	EN 14683 - Annex B 122, 124, 129	
BFE - 2	%	99,6	≥95	≥98	≥98	97	EN 14683 - Annex B 122, 124, 129	
BFE - 3	%	99,6	≥95	≥98	≥98	97	EN 14683 - Annex B 122, 124, 129	
BFE - 4	%	99,9	≥95	≥98	≥98	97	EN 14683 - Annex B 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 B	122, 124, 129
Mean Positive Control Count	cfu	2395	-	-	-	-	EN 14683 - Annex B	
Negative Control Count	cfu	<1	-	-	-	-	EN 14683 - Annex B	
Mean Particle Size (MPS)	µm	2,9	-	-	-	-	EN 14683 - Annex B	
<b>Microbial Limit - Bioburden</b>								
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

Positive 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 incubated 3 days at 30-35°C, then enumerated.

Yeast - Mould : Plates are incubated 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



## ANALYSIS REPORT

Report No. : **2011194E-R1**

Report Date : **02/06/2020**

**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 Enviromental 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 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 :  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 - Requirement 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 Tatlıpınar Sokak No: 13 Mart Plaza Kat: 2/A  
Kağıthane/İstanbul

Issue Date : 02/06/2020

Revision Date/No : -

\* The undersigned herewith declares 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

STL TEKNOLOJİ LTD. ŞTİ.  
Çatalmeşe Mah. Reşadiye Cad. 186 Sk. No: 18  
Alemdağ - Çekmeköy - İstanbul - TÜRKİYE  
Sarıgazi V.D.: 773 030 161 Te. Sic. No: 575043  
Mersis No: 0773030186100010  
<http://benceiyi.com> - [info@benceiyi.com](mailto:info@benceiyi.com)  
Tel.: 02163145521 Fax.: 02163145523



SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

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 SYSTEM CERTIFICATIONS

*Managing Director*



**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](http://www.siscertifications.com)  
The status of this certificate can be verified on "<http://www.siscertifications.co.in>".

Issue No.: 02

CERTIFICATE OF COMPLIANCE





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

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

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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**

SYNDICATE OF INTERNATIONAL SYSTEM

*Managing Director*



**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](http://www.siscertifications.com)  
The status of this certificate can be verified on "<http://www.siscertifications.co.in>".

Issue No.: 02





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

CE

CE ATTESTATION OF CONFORMITY

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

Class Simf: CLASS 1 / SINIF 1, NON STERILE

Description of Product :  
MEDICAL MASK  
TIBBİ MASKE

Manufactured by

STL TEKNOLOJİ 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:

  
Managing Director



**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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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](http://www.siscertifications.com)  
The status of this certificate can be verified on "<http://www.siscertifications.co.in>".

Issue No.: 02

CERTIFICATE OF REGISTRATION



# 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](mailto:info@staunchlyservices.com) Web : [www.staunchlyservices.com](http://www.staunchlyservices.com)

SMS/F109A/17/REV02

For precise and updated information concerning the present certificate mail to [info@staunchlyservices.com](mailto:info@staunchlyservices.com)

This Certificate is the property of Staunchly Management & System Services Private Limited and shall be returned immediately when demanded





# PACKAGING





THANK YOU!

