



medirol



Disposable Medical **KID'S FACE MASK**

DISPOSABLE MEDICAL **FACE MASK**

3-PLY EARLOOP

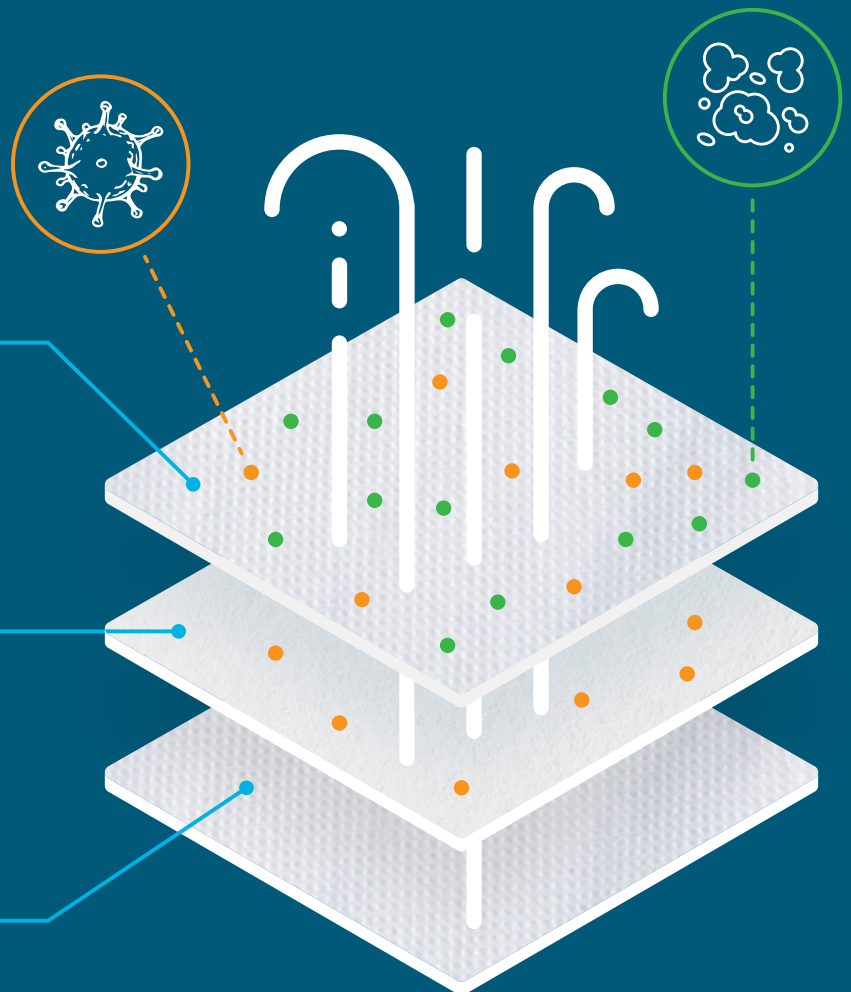


THREE LAYER PROTECTION

Non-Woven Fabric

Melt-Blown Filter

Non-Woven Fabric





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 - Requirementst 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 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

STL TEKNOLOJİ LTD. ŞTİ.
Çatalçeşme Mah. Reşadiye Cad. 186 Sk. No: 18
Alemdağ - Çekmeköy - İstanbul - TÜRKİYE
Sarıgazi V.D.: 773 030 1411 Tc. Sic. No: 575043
Mersis No: 0773030186100010
<http://benceiyyi.com> - info@benceiyyi.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 TORBASİ, 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 SYSTEI

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
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

TEKSTİL ÜRÜNLERİ, MEDİKAL KORUYUCU KIYAFET, MASKE, KORUYUCU TULUM, BONE, ELDİVEN, GALOŞ, ÖNLÜK, HASTA VE DOKTOR İÇİN AMELİYAT ÖNLÜĞÜ, SEDYE ÖRTÜSÜ, CESET TORBASİ, 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**

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.

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

Issue No.: 02



ACCREDITED
Management Systems
Certification Body





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS



CE ATTESTATION OF CONFORMITY

Related Directives :

MEDICAL DEVICES 93/42/EEC-----TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

Class Sınıf: 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



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
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 TORBASİ,
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

THANK YOU!

