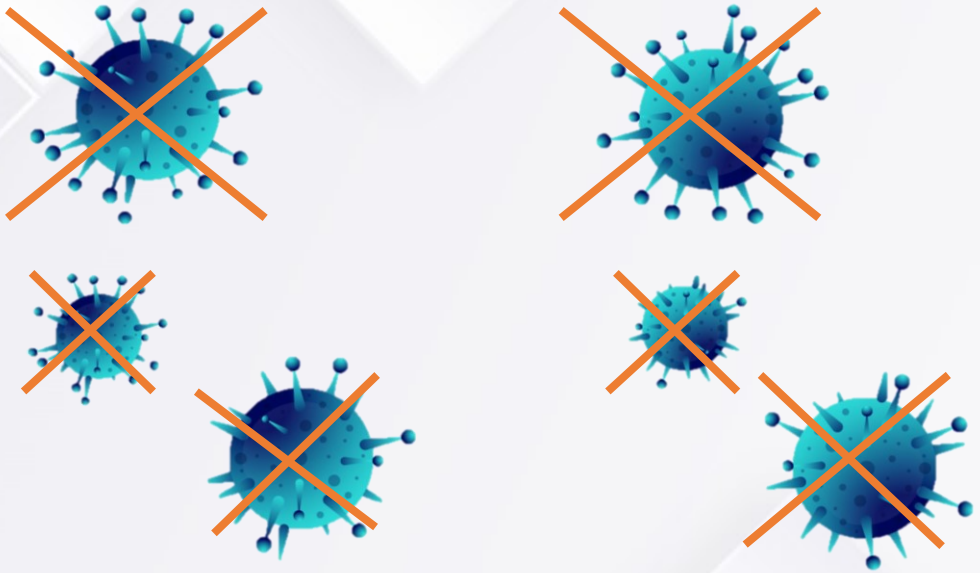
STR
BİYOTEKNOLOJİLERİ

Personal Protective Equipments



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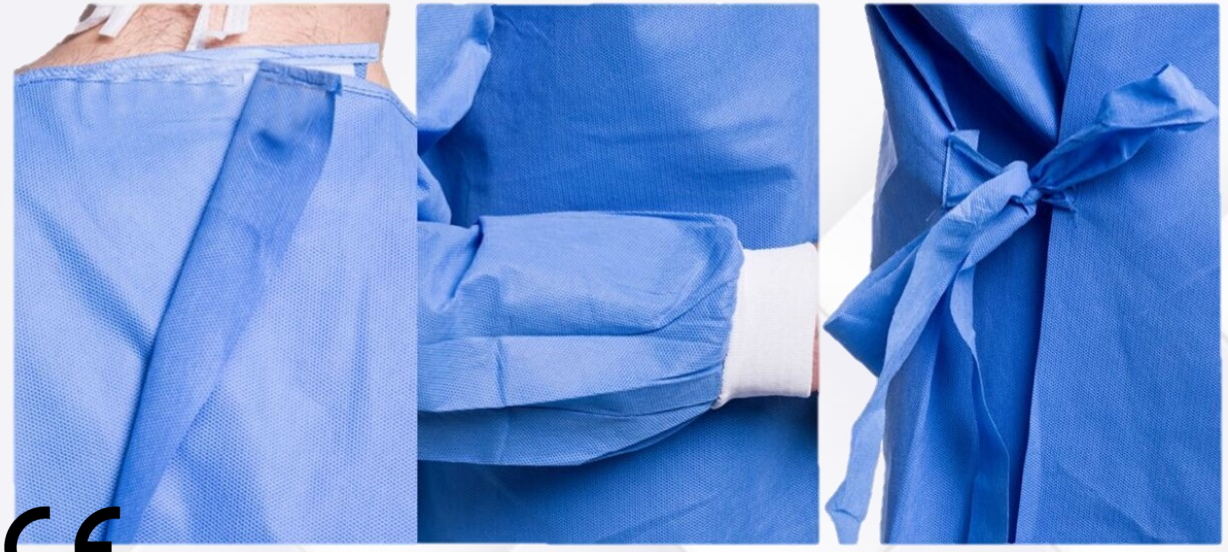
ISO 13485:2016

CE

STR BİYO TEKNOLOJİLERİ MEDİKAL İML.İTH.İHR.SAN.TİC.LTD.ŞTİ.
Adress: Mimarsinan Mah. Küçük Sanayi 27. Sok. No.2 Merkez,19100, Çorum TURKEY
Tel: +90 539 887 7515 E-Mail: info@strmedical.com Web: www.strmedical.com

Surgical Gowns

Product Description	Type/Model/Level	Sizes
Surgical Gown (30-40 GMS)	LEVEL I- II and III	Small, Medium, Large, X-Large, XX-Large



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Protective Coveralls

Product Description	Type/Model/Level	Sizes
Protective Coverall (56-60 GMS)	Type3-5/ 6	Small, Medium, Large, X-Large, XX-Large

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Protective Masks

Product Description	Type/Model/Level	Sizes
Disposable Protective Mask	2,3 and 4 Ply	Standard
Disposable Protective Mask	KN95 FFP2	Standard
Disposable Protective Mask	KN95 FFP3	Standard

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Covid19 Rapid Test Kits

- Covid19 Rapid Test Kit
- Detection of virus in 5 minutes
- CE Certified
- 25 Kits in 1 Box
- MoQ is 100,000 pcs

Carton dimension：**430*307*437mm (volume 0.05768m³)**
Weight for unit carton：**0.64kg**
Weight for 25T pack：**0.22kg**
Weight for unit carton with 25 boxes：**6.14KG**
Carton quantity：**2400pcs**
Product name： **SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)**

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Isolation Foot Wear

- SMS Non woven raw material
- Thread Sewing
- CE Certified raw material
- MoQ 50,000 pcs

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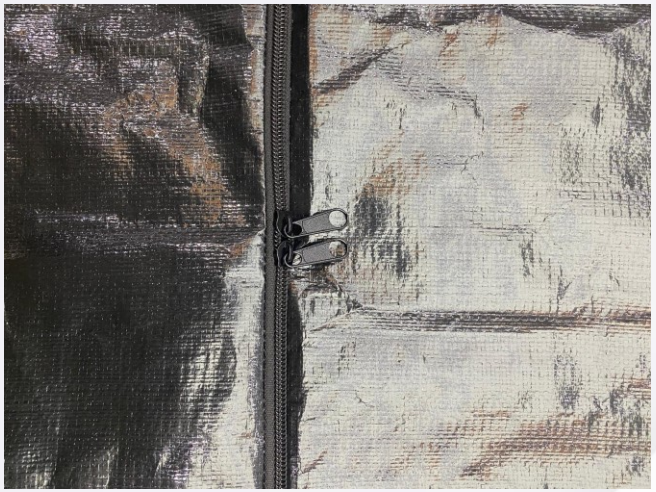
CE

Body Bags

- SMS Non woven laminated 135 GSM raw material
- Thread Sewing
- CE Certified raw material
- MoQ 10,000 pcs
- Adults Size: 80x220 cm
- Infant Size: 50x100 cm



FDA APPROVED GMP CERTIFIED ISO 13485:2016 CE

Head Cover

- SMS Non woven raw material
- Thread Sewing
- CE Certified raw material
- MoQ 10,000 pcs

FDA APPROVED

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Rewashable Masks

- ✓Made of microfiber raw material
- ✓Rewashable 30 times at 90 C
- ✓Resterilizable
- ✓High filtration and low inhaling resistance
- ✓Flexible design, dermal friendly

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Face Shield

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Certificates

FDA Registered Company

U.S. Department of Health & Human Services

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FDA U.S. FOOD & DRUG ADMINISTRATION

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SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

1 result found for **Establishment Registration**
or Business Trade Name : *STR BIYO*
Establishment Registration or FEI Number :
3017349359

New Search

Establishment Name		Registration Number	Current Registration Yr
STR BIYO TEKNOLOJILERI MEDIKAL LTD STI	TURKEY	3017349359	2020
• Gown, Examination - STR Isolation Gown			Manufacturer
• Non-Surgical Isolation Gown - STR Disposable Gown			Manufacturer
• Cover, Shoe, Operating-Room - STR Shoe Cover			Manufacturer
• Container, Specimen, Non-Sterile - STR Body Bag			Manufacturer
• Respirator, Surgical - STR Disposable 3 Ply Mask			Manufacturer
• Accessory, Surgical Apparel - STR Face Shield			Manufacturer
• Cap, Surgical - STR Head Cover			Manufacturer

FDA APPROVED GMP CERTIFIED ISO 13485:2016 CE

Certificates

CERTIFICATE

of Registration

CERTIFIED STAUNCHLY MANAGEMENT SYSTEM

This is to Certify that the

Medical Devices – Quality Management System

of

STR BİYO TEKNOLOJİLERİ MEDİKAL İMALAT İTHALAT VE İHRACAT SAN. TİC. LTD. ŞTİ.

MİMARSİNAN MAH. KÜÇÜK SANAYİ 27. SOK. NO:2 MERKEZ / ÇORUM / 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:

R&D, DESIGN, MANUFACTURING, SALES AND MARKETING OFORHOPEDIC PROSTHESIS, AUTOLOGOUS PRP, CGF AND PRP KITS, TUBES, STEMCELL KITS AND TUBES, GOWN, MASK, COVERALL.

ORTOPEDİK PROTEZLER, OTOLOG PRP, CGF VE PRF KİTLERİ, TÜPLERİNİN VE KÖK HÜCRE KİTLERİ VE TÜPLERİNİN, ÖNLÜK, MASKE, TULUMUN AR-GE, TASARIMI, İMALATI, SATIS VE PAZARLAMASI.

:: Certificate No :: TR50934H

Date of initial registration	20 February 2019
Date of this Certificate	05 March 2020
Surveillance audit on or before	19 February 2021
Recertification Due / Certificate expiry	19 February 2022

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

Director

IAS IAF

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/REV

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

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GMP CERTIFIED

ISO 13485:2016

CE

Certificates

Sertifika
Certificate

DSR CERTIFICATION

STR BİYO TEKNOLOJİLERİ MEDİKAL İMALAT İTHALAT VE İHRACAT SAN. TİC. LTD. ŞTİ.

MİMARSİNAN MAH. KÜÇÜK SANAYİ 27. SK. NO:2 MERKEZ / ÇORUM

DSR BELGELENDİRME tarafından denetlenmiş ve uygulamakta olduğu
İyi Üretim Uygulamaları Yönetim Sisteminin

is audited by DSR Certification and applied
Good Manufacturing Practices Management System meet the requirements of

GMP

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.
standard for the following activities.

HER TÜRLÜ TIBBİ CİHAZLARIN ARGE TASARIM İMALATI SATIŞI VE PAZARLAMASI

Sertifika No / *Certificate No:* **GMP-17.11.120**

13.11.2018	25.12.2019	24.12.2020
Sertifika Tarihi *Certificate Date*	Sertifika Son Basım Tarihi *Certificate Last Issue Date*	Belgelendirme Periyodu Bitiş Tarihi *Certification Period Expiration Date*

24.12.2020
Sertifika Geçerlilik Tarihi
Certificate Expiry Date

DSR CERTIFICATION
GMP CERTIFIED

ONAY
APPROVAL

FR-072 Yayın Tarihi:18.04.2017
Rev.No:01 Rev.Tarihi: 24.05.2018

Rev.00 / Revizyon Tarihi:

DSR ULUSLARARASI GÖZETİM VE BELGELENDİRME HİZMETLERİ LTD. ŞTİ.
Yeşilbağlar Mah. Selvili Sk. Helis Beyaz Ofis 2/1 A Blok No:207 PENDİK / İSTANBUL / TÜRKİYE Tel: +90 216 606 06 35
E-mail: info@dsrbelgelendirme.com.tr - Web: www.dsrbelgelendirme.com.tr

FDA APPROVED

GMP CERTIFIED

ISO 13485:2016

CE

Certificates

CERTIFICATE OF REGISTRATION

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

CE

CE ATTESTATION OF CONFORMITY

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

CLASS / SINIF : **CLASS 1 / SINIF 1, NON STERILE**

Description of Product:
MASK / MASKE

RegulationsAppliedacc. ToHarmonizedStandards:
EN ISO 13485:2016, EN 1041:2008+A1:2013, EN ISO 15223-1:2016, EN ISO 14971:2012, EN 62366-1:2015, EN 14683:2019

Trade Mark :
STR

Manufactured by

STR BİYO TEKNOLOJİLERİ MEDİKAL İMALAT İTHALAT VE İHRACAT SAN. TİC. LTD. ŞTİ.
MİMARSİNAN MAH. KÜÇÜK SANAYİ 27. SK. NO:2 MERKEZ / ÇORUM / TÜRKİYE

Certificate No.: SISTURCE042020657
Issue Date (Original): 04.05.2020
Issue Date(Latest): 04.05.2020
Expiry Date: 03.05.2021

CE

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.

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.: 01

APPROVED

13485:2016

Certificates

CERTIFICATE OF REGISTRATION

CE ATTESTATION OF CONFORMITY

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

CLASS / SINIF : **CLASS 1 / SINIF 1, NON STERILE**

Description of Product:
COVERALLS, GOWNS AND APRONS
TULUM VE ÖNLÜK

Trade Mark :
STR

Regulations Applied acc. To Harmonized Standards:
TS EN14362-1, TS EN 14126

Manufactured by

STR BİYO TEKNOLOJİLERİ MEDİKAL İMALAT İTHALAT VE İHRACAT SAN. TİC. LTD. ŞTİ.
MİMARSİNAN MAH. KÜÇÜK SANAYİ 27. SK. NO:2 MERKEZ / ÇORUM / TÜRKİYE

Certificate No.: SISTURCE042020659
Issue Date (Original): 04.05.2020
Issue Date(Latest): 06.05.2020
Expiry Date: 03.05.2021

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".

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Certificates

CERTIFICATE OF REGISTRATION

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

CE

CE ATTESTATION OF CONFORMITY

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

CLASS / SINIF : **CLASS 1 / SINIF 1, NON STERILE**

Description of Product:
INSPECTION GLOVES
MUAYENE ELDİVENİ

Trade Mark :
STR

Regulations Applied acc. To Harmonized Standards:
TS EN 455-1

Manufactured by

STR BİYO TEKNOLOJİLERİ MEDİKAL İMALAT İTHALAT VE İHRACAT SAN. TİC. LTD. ŞTİ.
MİMARSİNAN MAH. KÜÇÜK SANAYİ 27. SK. NO:2 MERKEZ / ÇORUM / TÜRKİYE

Certificate No.: SISTURCE042020658
Issue Date (Original): 04.05.2020
Issue Date(Latest): 06.05.2020
Expiry Date: 03.05.2021

CE

This Certificate is issued under the following conditions:

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

SIS CERT.

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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".

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UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-179

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 by

STR BİYO TEKNOLOJİLERİ MEDİKAL İMALAT İTHALAT VE İHRACAT SANAYİ TİCARET LİMİTED ŞİRKETİ

at the following address

Mimarsinan Mahallesi Küçük Sanayi 27. Sokak No:2 Merkez CORUM / TURKEY

EN 13795-1:2019 Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns

Brand Name: STR
Model: STRIZOLOZATION01
(Standard Performance)are tested according to the following initial type tests by the manufacturer

For the assessment of conformity, the following documents were also reviewed:
Laboratory test results for Microbial Penetration (wet/cry), Bioburden, Bursting and Tensile Strengths (wet/dry)

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 surgical gowns manufactured and designed for use to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. With this certificate, it is approved that the product fulfils all essential requirements and the related rules o' 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: performance level 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 09/07/2020 and valid until 08/07/2021 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 –09/07/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

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