Certificate

ELİTEX GİYİM ANONİM ŞİRKETİ

TEPEBAŞI MAH. ILISU CAD. NO:79
DARGEÇİT / MARDİN / TÜRKİYE

Has been assessed and found to Comply with the Requirements of:
Denetlenmiş ve aşağıdaki standartın gerekliliklerine uygunluğu görülmüştür:

ISO 22716:2008:GMP

GOOD MANUFACTURING PRACTICES

The GMP System is applicable to:
İyi Üretim Uygulamaları:

PRODUCTION, SALES AND EXPORTS OF MEDICAL TEXTILE PRODUCTS (MASK, OVERALLS, APRON) AND DISINFECTANT CLEANING PRODUCTS

MEDİKAL TEKSTİL ÜRÜNLERİ (MASKE, TULUM, ÖNLÜK) VE DEZENFEKTAN TEMİZLİK ÜRÜNLERİ ÜRETİMİ, SATIŞI VE İHRACATI

Certificate No: ISO/21149
Sertifika Numarası: ISO/21149

Date of Certification Audit: 14.04.2020
Denetim Tarihi: 14.04.2020

Date of Issue: 21.04.2020
Yayınlanma Tarihi: 21.04.2020

Date of Expiry: 20.04.2021
Son Geçerlilik Tarihi : 20.04.2021

1st Surveillance Audit : April 2021
1. Gözetim Denetim Tarihi : Nisan 2021
2nd Surveillance Audit : April 2022
2. Gözetim Denetim Tarihi : Nisan 2022

Qcs International Certifications Services Pvt. Ltd
Certificate of validity information E-mail: info@qcscert.com
mail to confirm

CERTIFICATE OF REGISTRATION

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate has been awarded to

ELİTEX GİYİM ANONİM ŞİRKETİ

TEPEBAŞI MAH. ILISU CAD. NO:79 DARGEÇİT / MARDİN / 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

PRODUCTION, SALES AND EXPORTS OF MEDICAL TEXTILE PRODUCTS (MASK, OVERALLS, APRON) AND DISINFECTANT CLEANING PRODUCTS

MEDİKAL TEKSTİL ÜRÜNLERİ (MASKE, TULUM, ÖNLÜK) VE DEZENFEKTAN TEMİZLİK ÜRÜNLERİ ÜRETİMİ, SATIŞI VE İHRACATI

Certificate Number: **SISTURQ0420202069**
Date of Issue of Original Certificate: **21.04.2020**
Date of Issue of latest certificate: **21.04.2020**
Expiry Date: **20.04.2021**

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

Issue No.: **01**

SIS CERT.

IAS ACCREDITED Management Systems Certification Body

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

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 / Sınıf: CLASS 1 / SINIF 1, NON STERILE

Description of Product : MASK / MASKE

Manufactured by

ELİTEX GİYİM ANONİM ŞİRKETİ
TEPEBAŞI MAH. ILISU CAD. NO:79 DARGEÇİT / MARDİN / TÜRKİYE

Certificate No.: SISTURCE042020424
Issue Date (Original): 21.04.2020
Issue Date(Latest): 21.04.2020
Expiry Date: 20.04.2021

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.

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Web:- http://www.siscertifications.co.in, www.siscertifications.com
The status of this certificate can be verified on "http://www.siscertifications.co.in".

SIS CERT.

Issue No.: **01**

CERTIFICATE
of Registration

This is to Certify that the

Medical Devices – Quality Management System

of

ELİTEX GİYİM ANONİM ŞİRKETİ

TEPEBAŞI MAH. ILISU CAD. NO:79 DARGEÇİT / MARDİN / 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:

PRODUCTION, SALES AND EXPORTS OF MEDICALTEXTILE PRODUCTS (MASK, OVERALLS, APRON) AND DISINFECTANT CLEANING PRODUCTS

MEDİKAL TEKSTİL ÜRÜNLERİ (MASKE, TULUM, ÖNLÜK) VE DEZENFEKTAN TEMİZLİK ÜRÜNLERİ ÜRETİMİ, SATIŞI VE İHRACATI

:: Certificate No :: TR51984H

Date of initial registration	**20 April 2020**
Date of this Certificate	**20 April 2020**
Surveillance audit on or before	**19 April 2021**
Recertification Due / Certificate expiry	**19 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

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 / Sınıf: CLASS 1/ SINIF 1 / NON STERILE

Description of Product :
PROTECTIVE OVERALLS
KORUYUCU TULUM

Manufactured by

ELİTEX GİYİM ANONİM ŞİRKETİ
TEPEBAŞI MAH. ILISU CAD. NO:79 DARGEÇİT / MARDİN / TÜRKİYE

Certificate No.: SISTURCE042020559
Issue Date (Original): 28.04.2020
Issue Date(Latest): 28.04.2020
Expiry Date: 27.04.2021

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

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SIS CERT.

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

Issue No.: **01**

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 / Sınıf: CLASS 1/ SINIF 1 / NON STERILE

Description of Product :
PROTECTIVE APRON
KORUYUCU ÖNLÜK

Manufactured by

ELİTEX GİYİM ANONİM ŞİRKETİ
TEPEBAŞI MAH. ILISU CAD. NO:79 DARGEÇİT / MARDİN / TÜRKİYE

Certificate No.: SISTURCE042020558
Issue Date (Original): 28.04.2020
Issue Date(Latest): 28.04.2020
Expiry Date: 27.04.2021

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Managing Director

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SIS CERT.

Issue No.: **01**

LİDERSAN AMBALAJ

ANALİZ SERTİFİKASI
(CERTIFICATE OF ANALYSIS)

		TARİH:	22.04.2020
ÜRÜN ADI (PRODUCT NAME)	164 CM. 66 GSM. BREATHABLE BASKISIZ LAMİNELİ TXB		
ÜRÜN KODU (PRODUCT CODE)	UBRT1323		
SİPARİŞ NO (ORDER NUMBER)	M20200000000909		

TEST SONUÇLARI
(TEST RESULTS)

ÖZELLİKLER *(SPECIFICATIONS)*	**BİRİM** *(UNIT)*	**DEĞER** *(VALUE)*	**TOLERANS** *(TOLERANCE)*	**GERÇEKLEŞEN DEĞER** *(ACTUAL VALUE)*	**TEST METODU** *(TEST METHOD)*
EN (WIDTH)	cm	164	±1	164	**LIDERSAN TEST**
KALINLIK(THICKNESS)	g/m²	66	±%10	66	**LIDERSAN TEST**
PE FILM GSM	g/m²	29	±%10	29	**LIDERSAN TEST**
NW GSM	g/m²	35	±%10	35	**LIDERSAN TEST**
DELAMINASYON KUVVETI (PEEL FORCE)	N/25 mm	> 1,5	±%10	1,7	**LIDERSAN TEST**
GERİLME DİRENCİ (TENSILE STRENGH)	MD (N/25mm)	73	±10	74	**ASTM D 882**
	TD (N/25mm)	28	±10	24	**ASTM D 882**
PE FİLM WVTR	gm/(m²-gün)	6000-8000	±500	6800	**ASTM D 6701-01**

Storeage Condition ; Keep in cool,dry place away from open flame and sunshine
Guaranteed storage time: 1 year after manufacturing

AÇIKLAMA -DEFINATION(*Özel Müşteri Talepleri-Special Customer Demand*)

ONAY / APPROVAL
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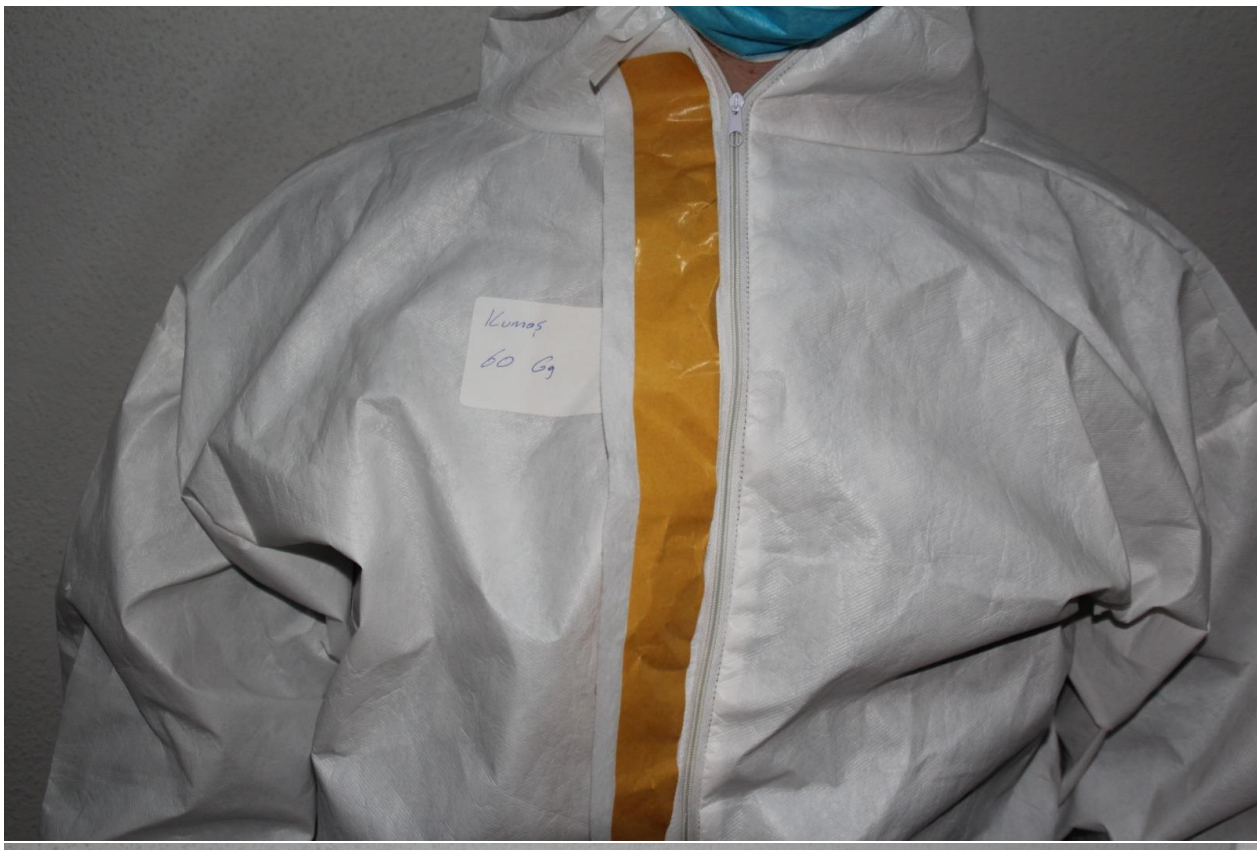
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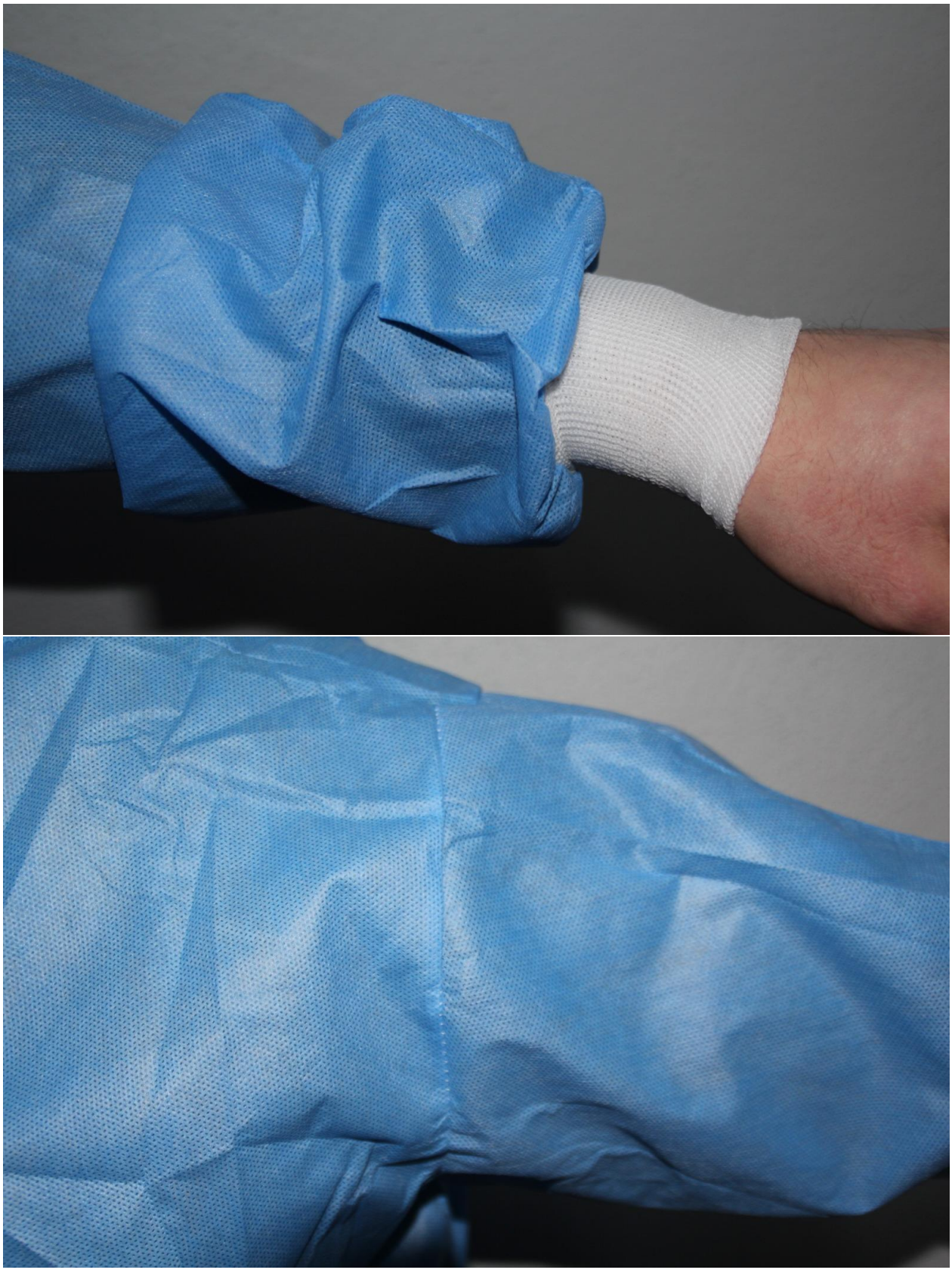

PRICE LIST

MEDICAL PROTECTIVE SUIT: 50,000 UNIT PER DAY
SURGICAL MASK: 250,000 UNIT PER DAY
MEDICAL APRON: 50,000 UNIT PER DAY

	SURGICAL MASK: 250,000 UNIT PER DAY	0.40 USD
	MEDICAL APRON: 50,000 UNIT PER DAY	2 USD
	MEDICAL PROTECTIVE SUIT: 50,000 UNIT PER DAY	7.00 USD