



STERIL SAGLIK URUNLERI

SURGICAL/ISOLATION
GOWNS CATALOG



STERIL SAGLIK URUNLERI

Ziyapasa Mh 67132 Sok Gulmen Apt Asma K D:1
Seyhan/Adana, Turkey, 01001

www.sterilsaglik.com



NONWOVEN DISPOSABLE GOWNS

AAMI -LEVEL 1

REF: SSU-901

Item name	Disposable NonSterile Surgical Gown
Style	SS Surgical Gown with knit cuff
Material	SS 30 gsm (Spunbond+Spunbond)
Size	M-L-XL-XXL
Colour	Blue
Certificate	CE, FDA

Level 1	Used for MINIMAL risk situations	Basic care, standard hospital medical unit
	Provides a slight barrier to small amounts of fluid penetration	
	Single test of water impacting the surface of the gown material is conducted to assess barrier protection performance.	





NONWOVEN DISPOSABLE GOWNS

AAMI -LEVEL 2

REF: SSU-902

Item name	Nonwoven Disposable Gowns
Style	SS Surgical Gown with knit cuff
Material	SS 40 gsm (Spunbond+Spunbond)
Size	M-L-XL-XXL
Colour	Blue
Certificate	CE,FDA

Level 2	Used in LOW risk situations	Blood draw from a vein, Suturing, Intensive care unit, Pathology lab
	Provides a barrier to larger amounts of fluid penetration through splatter and some fluid exposure through soaking	
	Two tests are conducted to assess barrier protection performance:	
	Water impacting the surface of the gown material	



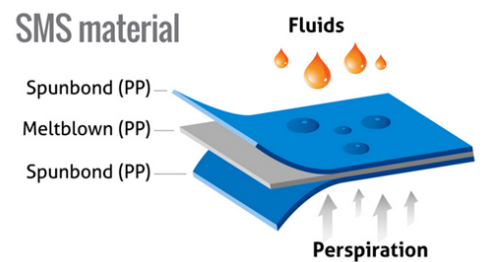


NONWOVEN DISPOSABLE ISOLATION GOWN

AAMI -LEVEL 3

REF: SSU-903

Item name	Nonwoven Disposable Isolation Gown	
Style	SMS Isolation Gown with knit cuff	
Material	Material: SMS 40 gsm	
Size	M-L-XL-XXL	
Colour	Blue	
Certificate	CE,FDA	
Level 3	Used in MODERATE risk situations	Arterial blood draw, Inserting an IV, Emergency Room, Trauma
	Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soaking than Level 2	
	Two tests are conducted to test barrier protection performance:	
	Water impacting the surface of the gown material	





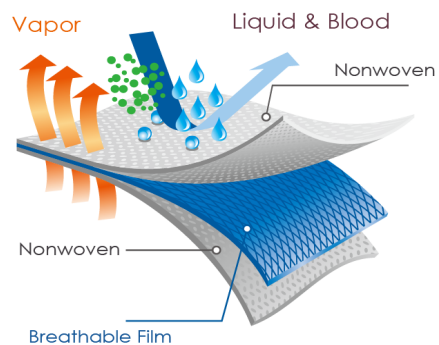
NONWOVEN DISPOSABLE ISOLATION GOWN

AAMI -LEVEL 4

REF: SSU-904

Item name	Nonwoven Disposable Isolation Gown
Style	SMS Isolation Gown with knit cuff
Material	Material: SMS 40 gsm + PE Breathable 19 gsm Laminated Film
Size	M-L-XL-XXL
Colour	Blue
Certificate	CE,FDA

Level 4	Used in HIGH risk situations	Pathogen resistance, Infectious diseases (non-airborne), Large amounts of fluid exposure over long periods
	Prevents all fluid penetration for up to 1 hour	
	May prevent VIRUS penetration for up to 1 hour	
	In addition to the other tests conducted under levels 1-3, barrier level performance is tested with a simulated blood containing a virus. If no virus is found at the end of the test, the gown passes.	



PRESSURE TESTS





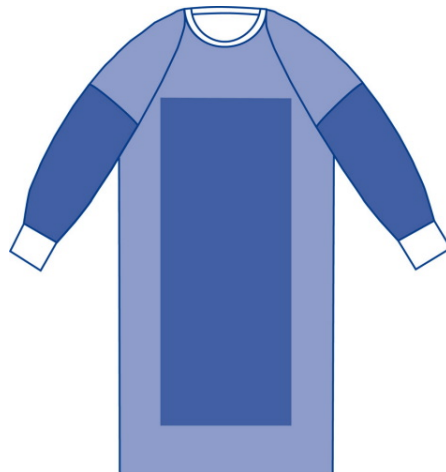
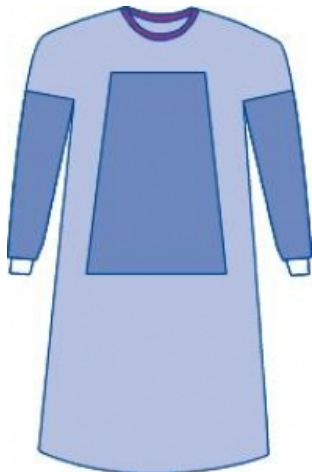
NON-SURGICAL GOWNS- REINFORCED

Item name	Nonwoven Disposable Isolation Gown- Reinforced
Style	Non-Surgical Gowns- Reinforced
Material	Material: SMS 40 gsm + Reinforced Coating Material
Size	M-L-XL-XXL
Colour	Blue
Certificate	CE,FDA



REF: SSU-RF1

REF: SSU-RF2



CERTIFICATE • CERTIFICADO • CERTIFICAT • 證書 • 証書 • CERTIFIKAT • CERTIFICATE



TESTUV CERTIFICATE

EC DECLARATION OF CONFORMITY

Manufacturer :
 Steril Sağlık Ürünleri- Zeynel Abidin Savrun
Address :
 Ziyapaşa Mah. 67132 Sk. Gülmen Apt Asma Kat D: 1
 Seyhan Adana Turkey
Products :
 Disposable Surgical Gowns- Sterile and Non Sterile
Type:
 Level 1-2-3-4
Related Standards :
 EN 13795 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
 EN ISO 14971 Medical devices - Application of risk management to medical devices
 EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
 EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
 EN 1041+A1 Information supplied by the manufacturer of medical devices
 EN ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

For the above products, the technical file and base product provided by the manufacturer is prepared on the basis of a voluntary test in accordance with the Personal Protective Equipment Directive 2016/425/EU basic protection requirements. The CE mark shown below can be used on the product at the discretion of the company, after the preparation of the necessary technical documents and declaration of conformity, and as long as other relevant directives and standards are complied with.
The use of CE marking is at the discretion of the company.

Certificate Publication Date: 01.07.2020
Certificate Expiry Date: 30.06.2021
Certificate Number: 20051187

TESTUV Sp. z o.o. Sp. k | Ludzka 13/10 Warszawa, Poland | info@testuv.com | www.testuv.com

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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

Establishment Registration & Device Listing

1 result found for Owner Operator Number : 10075476

Establishment Name	Registration Number	Current Registration Yr
STERIL_SAGLIK_URUNLERI TURKEY	No number listed	2020
Sub_Surgical - Covered Suit 1		Manufacturer
Non-Surgical Isolation Gown - Gown 1, Gown 2, Gown 3, Gown 4		Manufacturer

Can't find what you're looking for? [Try a new search](#)

Page Last Updated: 06/29/2020
 Note: If you need help accessing information in different file formats, see instructions for Downloading Viewers and Players.
 Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Пусловје | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية

U.S. Food and Drug Administration
 1093 New Hampshire Avenue
 Combination Products Advisory Committee
 U.S. Department of Health & Human Services



Certificate of Registration 2020

This is to certify the registration of

Steril Saglik Urunleri
Ziyapasa Mh 67132 Sok Gulmen Apt Asma K-D:1
Seyhan,Adana,01001, Turkey

with U.S Food and Drug Administration as Required by 21 CFR Part 207 is successfully completed by
FDA Advising Group, with the information provide by

DUNS Number :	533147979
Date of Registration :	06/17/2020
Date of Expiration :	12/31/2020
Owner/Operator Registration # :	10075476
Certificate Number :	12270034

This certificate does not make representations or warranties to any person or entity other than named certificate holder, it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S food and Drug Administration. FDA Advising Group LLC. Assumes no liability to any person or entity in connection with the foregoing.
 The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. FDA Advising Group LLC, is not affiliated with the U.S Food and Drug Administration.

FDA Advising Group
 7750 Oleachobee Blvd Ste #4-857 West Palm Beach, FL 33411
 fdaadvisinggroup.com

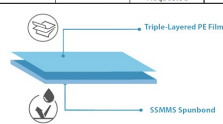
Hector L. Matos Jr.
 President
 FDA Advising Group LLC
 Dated: **06/17/2020**

GÜLSAN

**ÜRÜN SPEKT FORMU
(MATERIAL SPECIFICATION FORM)**

TEST (REQUIREMENT)	TEST METODU (TEST METHOD)	BİRİM (UNITS)	HEDEF (TARGET)	VERSİYON NO (VERSION NO)	0
g/m ² (Toplam) Grammage (Total)	WSP 130.1	g/m ²	55.0	52.0	58.0
MD Tensite at Peak	WSP 110.4	N/25mm	48.0	43.0	-
MD Süreme MD Elongation at Peak	WSP 110.4	%	58.0	48.0	68.0
CD Tensite at Peak	WSP 110.4	N/25mm	28.0	23.0	-
CD Süreme CD Elongation at Peak	WSP 110.4	%	58.0	48.0	68.0
Su Sütüsü Hydrostatic Head	WSP 70.8	mmSS	2,000	1,900	-
Gloss Level	ASTM D2457	Gloss unit	4.0	3.0	5.0
Opasite Opacity	GÜLSAN	%	70.0	65.0	75.0
Kalınlık Thickness	GÜLSAN	mm	0.220	0.190	0.250
Rulo Eni Roll Width	GÜLSAN	mm	Talep Edilen Requested	-3	3

Ürün Katmanları (Layers of the Material)



Triple-Layered PE Film
SSMMS Spunbond

KALİTE KONTROL MÜDÜRÜ
(QUALITY CONTROL MANAGER)

Erkan ÇELİK

ARGE UZMANI
(R&D SPECIALIST)

İbrahim ERKOL

İŞLETME MÜDÜRÜ
(PLANT MANAGER)

Kadir TAMER



accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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

Establishment Registration & Device Listing

1 result found for Establishment Registration or Business Trade Name: steril saglik

Establishment Name	Registration Number	Current Registration Yr
STERIL SAĞLIK ÜRÜNLERİ TURKEY	No number listed	2020
Sub: Surgical - Coverall Suit 1		Manufacturer
Non-Surgical Isolation Gown - Gown 1; Gown 2; Gown 3; Gown 4		Manufacturer

Page Last Updated: 06/22/2020
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Pycckий | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية | English

U.S. Food and Drug Administration
10903 New Hampshire Avenue

UNIVERSAL CERTIFICATION
NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 673

Electromagnetic Protection Clothing against Infective Agents;
Type 5-B Providing Protection to the Full Body against Airborne Solid Particulates
Type 6-B Offering Limited Protective Performance against Liquid Chemicals

STERİL SAĞLIK ÜRÜNLERİ - ZEYNEL ABİDİN SAVRUN
Ziyyapaşa Mahallesi 67132 Sokak Gülmen Apartmanı Asma Kat D:1 Seyhan ADANA / TÜRKİYE

EN 14126:2003/AC:2004, EN ISO 13982-1:2004/A1:2008, EN ISO 13982-2:2004, EN 13449-4:2004

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition
Brand Name: MICROSAFE, Model: PREMIER CA-506
Resistance to penetration by contaminated liquids under hydrostatic pressure: Class 2
Resistance to penetration by infective agents due to mechanical contact with substances containing concentrated liquids: Class 1
Resistance to penetration by concentrated liquid aerosols: Class 1
Resistance to penetration by concentrated solid particulates: Class 2

Here by the manufacturer is allowed to use notified body number (2163) and can its CE mark, as shown below, on the Category III product models given above, with:

- Issuing appropriate EU Declaration of Conformity according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 9
- Ongoing successful performance in reference of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonized standards, issued by amendments based on Annex T (Module CD) or Annex U (Module DU) of the regulation no later than 1 year from the beginning of serial production.

This certificate is initially issued on 11.06.2020 and will be valid for 3 years if there is no change in the relevant harmonized standard affecting the essential health and safety requirements

CE 2163

ŞEHİR KACMAZ
UNIVERSAL CERTIFICATION
Director

WQR WORLD QUALITY REGISTRAR

CERTIFICATE

Nr: W-200633-Q

Steril Sağlık Ürünleri- Zeynel Abidin Savrun

Ziyyapaşa Mah. 67132 Sk. Gülmen Apt. Asma Kat D: 1 Seyhan Adana Türkiye Turkey

This certificate is issued for the above-mentioned company according to the following scope given by the WQR Certification.
Bu sertifikayı yukarıdaki şirket için aşağıdaki kapsamda WQR Belgelendirme Enstitüsü vermiştir.

ISO 9001:2015

Quality Management System

Scope of Certification / Belgelendirme Kapsamı:
Manufacturing and Sales of Disposable and Reusable Medical Products
Tutk Kullandırma ve Yeniden Kullandırılabilir Medikal Ürünlerin İstisna ve Satış

Release Date / Yayın Tarihi: 22.06.2020
Last Issue Order / Son İstisna Tarihi: 22.06.2020
Expiry Date / Geçerlilik Tarihi: 21.06.2021
Period Exp. Date / İstisna Tarihi: 21.06.2023

WQR International Certification Ltd.
www.wqr.com.tr | info@wqr.com.tr

ACCREDITED INTERNATIONAL ISO 9001 QUALITY MANAGEMENT

WQR WORLD QUALITY REGISTRAR

CERTIFICATE

Nr: W-200633

Steril Sağlık Ürünleri- Zeynel Abidin Savrun

Ziyyapaşa Mah. 67132 Sk. Gülmen Apt. Asma Kat D: 1 Seyhan Adana Türkiye Turkey

This certificate is issued for the above-mentioned company according to the following scope given by the WQR Certification.
Bu sertifikayı yukarıdaki şirket için aşağıdaki kapsamda WQR Belgelendirme Enstitüsü vermiştir.

ISO 13485:2016

Medical Devices Quality Management System

Scope of Certification / Belgelendirme Kapsamı:
Manufacturing and Sales of Disposable and Reusable Medical Products
Tutk Kullandırma ve Yeniden Kullandırılabilir Medikal Ürünlerin İstisna ve Satış

Release Date / Yayın Tarihi: 22.06.2020
Last Issue Order / Son İstisna Tarihi: 22.06.2020
Expiry Date / Geçerlilik Tarihi: 21.06.2021
Period Exp. Date / İstisna Tarihi: 21.06.2023

WQR International Certification Ltd.
www.wqr.com.tr | info@wqr.com.tr

ACCREDITED INTERNATIONAL ISO 13485 MEDICAL DEVICES