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SURGICAL/ISOLATION GOWNS CATALOG





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	



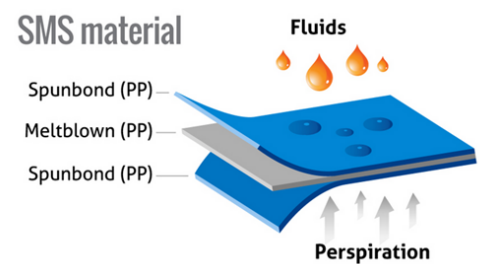


NONWOVEN DISPOSABLE ISOLATION GOWN

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	





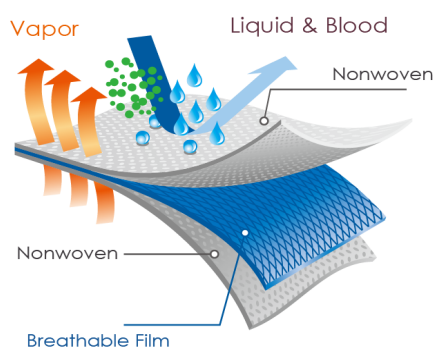
NONWOVEN DISPOSABLE ISOLATION GOWN

AAMI -LEVEL 4

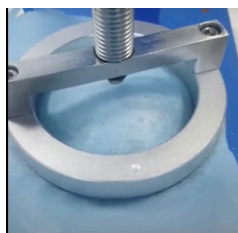
REF: SSU-904

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



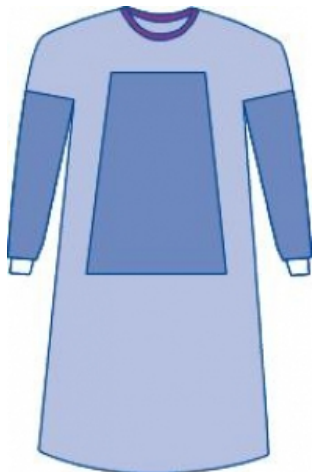


NON-SURGICAL GOWNS- REINFORCED

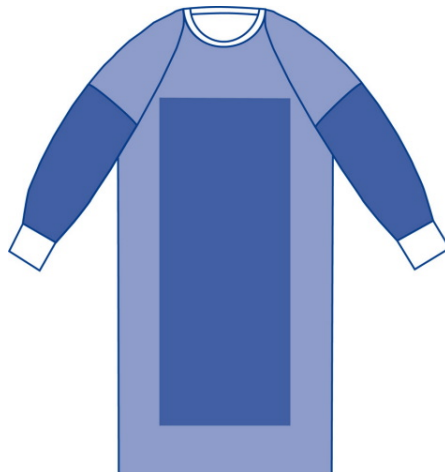
Item name	Nonwoven Disposable Isolation Gown- Reinforced
Style	Non-Surgical Gowns- Reinforced
Material	Material: SMS 40 gsm + Reinforced Coating Material
Size	M-L-XL-XXL
Colour	Blue
Certificate	CE,FDA

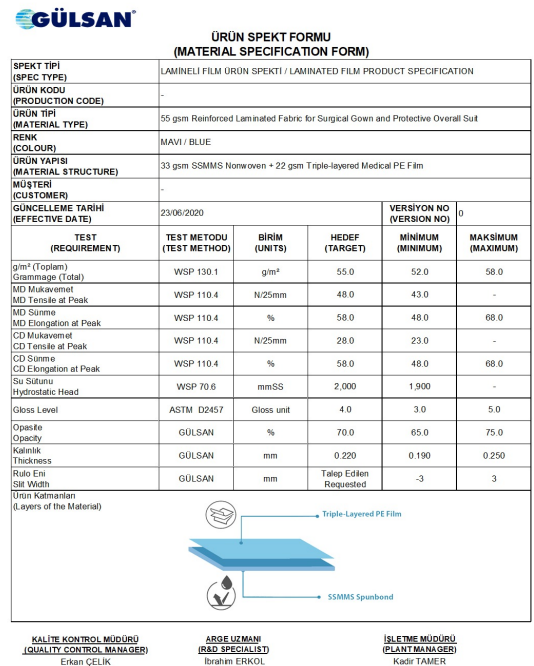
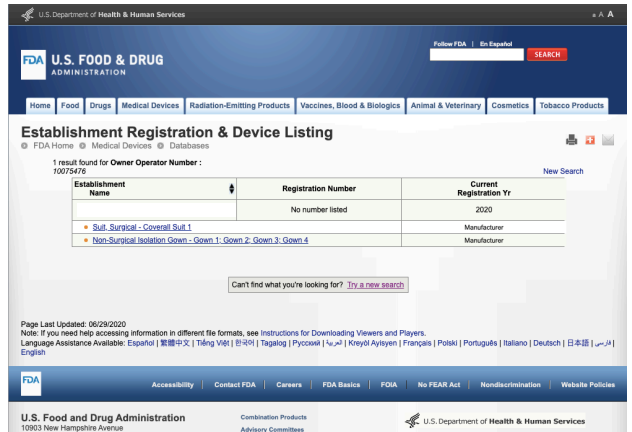
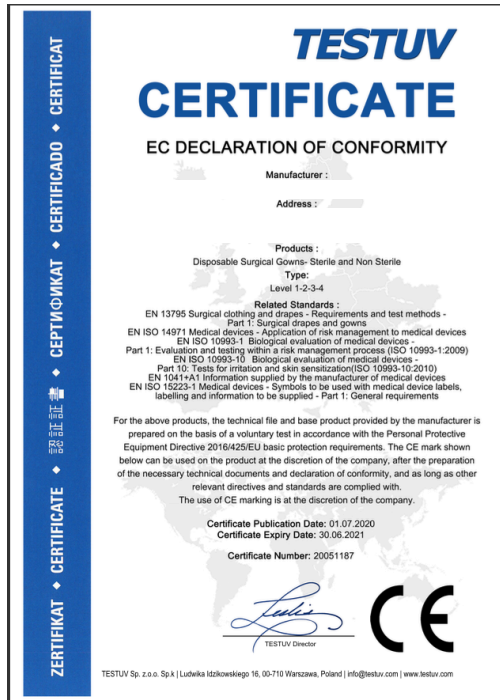


REF: SSU-RF1



REF: SSU-RF2







accessdata.fda.gov/scripts/cdrh/cfdocs/CTRL/r1.cfm

U.S. Department of Health & Human Services

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Establishment Registration & Device Listing

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

Establishment Name	Registration Number	Current Registration Yr
Sut. Surgical - Coverall Suit 1	No number listed	2020
Non-Surgical Isolation Gown - Gown 1; Gown 2; Gown 3; Gown 4		Manufacturer

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

Combination Products
Advisory Committees

U.S. Department of Health & Human Services

UNIVERSAL

UNIVERSAL CERTIFICATION
NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 673

Electrostatic Protective 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

are tested and evaluated according to
EN 14126:2003/A1:2004, EN ISO 13982-1:2004/A1:2004, EN 13054:2005/A1:2005, EN 13450-4:2005

Based on the type examination conducted with the evaluation of test reports, technical file according to
Personal Protective Equipment Regulation (EU) 2016/425 Annex 1, 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
contaminated liquids: Class 1
Resistance to penetration by contaminated liquid aerosols: Class 1
Resistance to penetration by contaminated solid particles: Class 2

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

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

This certificate is initially issued on 11/05/2020 and will be valid for 5 years if there is no change in the relevant harmonized standard affecting the essential health and safety requirements

CE 2163

Signature: *[Signature]*
Sait KACMAZ
UNIVERSAL CERTIFICATION
Director

Many Road Station Kuyucuk Street 22 Blok No: 00000 Tekirdag/Trakya - TURKEY T: +90 224 431 00 00
www.universalcert.com

WQR
WORLD QUALITY REGISTRAR

CERTIFICATE

Nr: W-200633-Q

ISO 9001:2015
Quality Management System

Scope of Certification / Belgelendirme Kapsamı
Manufacturing and Sales of Disposable and Reusable Medical Products
341 Kuluveçir ve Yeniden Kuluveçirle Medikal Ürünlerin Üretimi ve Satışı

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

Signature: *[Signature]*
DIRECTOR
WQR International Certification Ltd.
www.wqr.com.tr | info@wqr.com.tr

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Bu belgenin geçerliliği wqr.com.tr.tr adresinde on-line olarak kontrol edilebilir.

WQR
WORLD QUALITY REGISTRAR

CERTIFICATE

Nr: W-200633

ISO 13485:2016
Medical Devices Quality Management System

Scope of Certification / Belgelendirme Kapsamı
Manufacturing and Sales of Disposable and Reusable Medical Products
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