CATÁLOGO DE BATAS QUIRÚRGICAS/AISLAMIENTO

PROTECTIVE HOSPITAL EQUIPMENTS

MICROSAFE®

AAMI -LEVEL 1

REF: SSU-901

BATAS QUIRURGICAS AAMI- NIVEL 1

Nombre del artículo	Bata quirúrgica no estéril desechable de tejido sin tejer
Estilo	Bata quirúrgica SS con puño de punto
Material	SS 30 gsm (Spunbond + Spunbond)
Tamaño	M-L-XL-XXL
Color	Azul
Certificado	CE, FDA

Nivel 1	Se utiliza para situaciones de riesgo MINIMAL	Atención básica, unidad médica hospitalaria estándar
	Proporciona una ligera barrera a pequeñas cantidades de penetración de fluidos	
	Se realiza una sola prueba de agua que afecta a la superficie del material de la bata para evaluar el rendimiento de la protección de la barrera.	

BATAS QUIRURGICAS AAMI- NIVEL 2 . REF.SSU-902

AAMI -LEVEL 2

REF: SSU-902

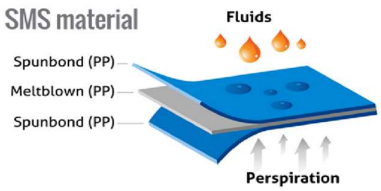
Nombre del artículo	Batas desechables de tejido sin tejer	
Estilo	Bata quirúrgica SS con puño de punto	
Material	SS 40 gsm (Spunbond + Spunbond)	
Tamaño	M-L-XL-XXL	
Color	Azul	
Certificado	CE,FDA	
Nivel 2	Utilizado en situaciones de BAJO riesgo	Extracción de sangre de en vena, Sutura, Unidad de Cuidados Intensivos, Laboratorio de Patología
	Proporciona una barrera a mayores cantidades de penetración de fluidos a través de salpicaduras y cierta exposición de líquidos a través del remojo	
	Se realizan dos pruebas para evaluar el rendimiento de la protección de barreras:	
	Agua que afecta a la superficie del material de la bata	

BATA DE AISLAMIENTO NIVEL 3 REF.SSU-903

AAMI -LEVEL 3

REF: SSU-903

Nombre del artículo	Bata de aislamiento desechable de tejido sin tejer	
Estilo	Bata de aislamiento SMS con puño de punto	
Material	Material: SMS 40 gsm	
Tamaño	M-L-XL-XXL	
Color	Azul	
Certificado	CE,FDA	
Nivel 3	Utilizado en situaciones de riesgo MODERADO	Extracción de sangre arterial, Insertar una vía intravenosa,, Sala de Emergencias, Trauma
	Proporciona una barrera a mayores cantidades de penetración de fluidos a través de salpicaduras y una exposición más fluida a través del remojo que el Nivel 2	
	Se realizan dos pruebas para probar el rendimiento de la protección de barreras:	
	Agua que afecta a la superficie del material de la bata	



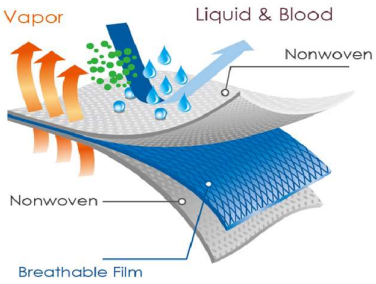
AAMI -LEVEL 4

REF: SSU-904

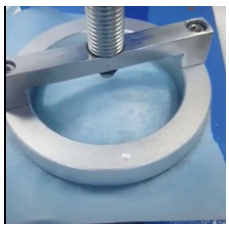
Bata de aislamiento desechable

Nombre del artículo	Bata de aislamiento desechable tejido sin tejer.
Estilo	Bata de aislamiento SMS con puño de punto
Material	Material: SMS 40 gsm + PE Polietileno transpirable 19 gsm película laminada
Tamaño	M-L-XL-XXL
Color	Azul
Certificado	CE,FDA

Nivel 4	Utilizado en situaciones de alto riesgo	Resistencia a patógenos, Enfermedades infecciosas (no en el aire), Grandes cantidades de exposición de líquidos largos períodos
	Previene toda la penetración de fluidos durante un máximo de 1 hora	
	Puede prevenir la penetración de VIRUS hasta 1 hora	
	Además de las otras pruebas realizadas en los niveles 1 a3, el rendimiento del nivel de barrera se prueba con una sangre simulada que contiene un virus. Si no se encuentra ningún virus al final de la prueba, la bata pasa.	



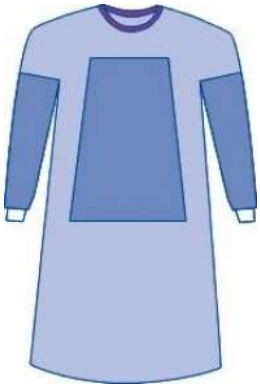
TEST DE PRESION

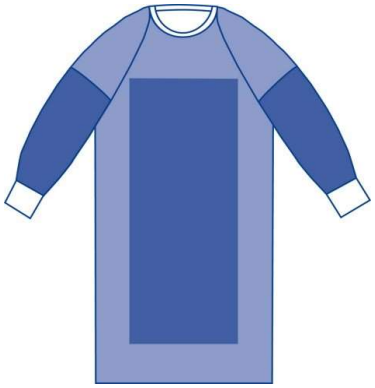


BATAS NO QUIRURGICAS REFORZADAS

Nombre del artículo	Bata de aislamiento desechable no tejido reforzado
Estilo	Batas no quirúrgicas- Reforzadas
Material	Material: SMS 40 gsm + Material de coaiting reforzado
Tamaño	M-L-XL-XXL
Color	Azul
Certificado	CE,FDA

REF: SSU-RF1 REF: SSU-RF2





ZERTIFIKAT ◆ CERTIFICATE ◆ 認証 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TESTUV

CERTIFICATE

EC DECLARATION OF CONFORMITY

Manufacturer :

Address :

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 Director

CE

TESTUV Sp. z.o.o. Sp.k | Ludwika Idzikowskiego 16, 00-710 Warszawa, Poland | info@testuv.com | www.testuv.com

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U.S. Department of Health & Human Services

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1 result found for **Owner Operator Number :** 10075476

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Establishment Name	Registration Number	Current Registration Yr
	No number listed	2020
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• 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
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Certificate of Registration 2020

This is to certify the registration of

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/OperatorRegistration # :	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.

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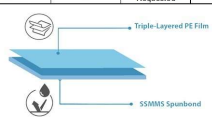
FDA Advising Group
7750 Okeechobee Blvd Ste #4-857 West Palm Beach, FL 33411
fdaadvisinggroup.com

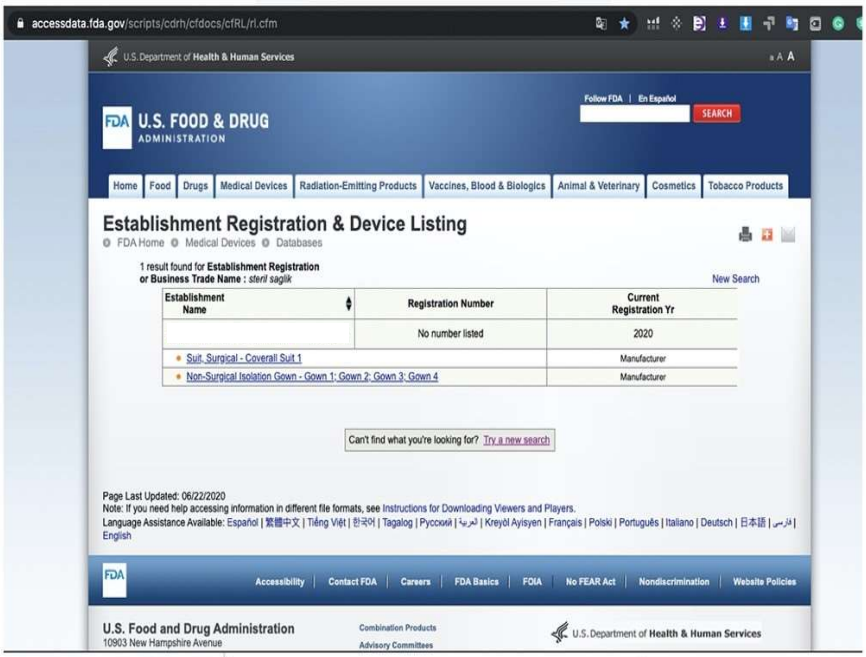
Hector I. Matos Jr.
President
FDA Advising Group LLC
Dated: **06/17/2020**

GÜLSAN

ÜRÜN SPEKT FORMU
(MATERIAL SPECIFICATION FORM)

SPEKT TİPİ (SPEC TYPE)	LAMİNELİ FİLM ÜRÜN SPEKTİ / LAMINATED FILM PRODUCT SPECIFICATION				
ÜRÜN KODU (PRODUCTION CODE)	-				
ÜRÜN TİPİ (MATERIAL TYPE)	55 gsm Reinforced Laminated Fabric for Surgical Gown and Protective Overall Suit				
RENK (COLOUR)	MAVİ / BLUE				
ÜRÜN YAPISI (MATERIAL STRUCTURE)	33 gsm SSMMS Nonwoven + 22 gsm Triple-layered Medical PE Film				
MÜŞTERİ (CUSTOMER)	-				
GÜNCELLEME TARİHİ (EFFECTIVE DATE)	23/06/2020			**VERSİYON NO (VERSION NO)**	0
TEST (REQUIREMENT)	**TEST METODU (TEST METHOD)**	**BİRİM (UNITS)**	**HEDEF (TARGET)**	**MİNİMUM (MINIMUM)**	**MAKSİMUM (MAXIMUM)**
g/m² (Toplam) Grammage (Total)	WSP 130.1	g/m²	55.0	52.0	58.0
MD Mukavemet MD Tensile at Peak	WSP 110.4	N/25mm	48.0	43.0	-
MD Sünme MD Elongation at Peak	WSP 110.4	%	58.0	48.0	68.0
CD Mukavemet CD Tensile at Peak	WSP 110.4	N/25mm	28.0	23.0	-
CD Sünme CD Elongation at Peak	WSP 110.4	%	58.0	48.0	68.0
Su Sütunu Hydrostatic Head	WSP 70.6	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 Slit Width	GÜLSAN	mm	Talep Edilen Requested	-3	3
Ürün Katmanları (Layers of the Material)					

KALİTE KONTROL MÜDÜRÜ (QUALITY CONTROL MANAGER)	ARGE UZMANI (R&D SPECIALIST)	İŞLETME MÜDÜRÜ (PLANT MANAGER)
Erkan ÇELİK	İbrahim ERKOL	Kadir TAMER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No number listed | 2020
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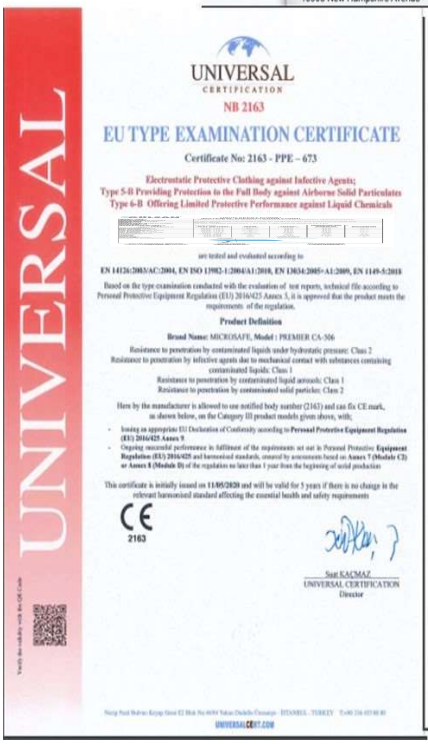
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UNIVERSAL CERTIFICATION
NB 2163
EU TYPE EXAMINATION CERTIFICATE
Certificate No: 2163 - PPE – 673
Electrostatic Protective Clothing against Infective Agents;
Type 5-B Providing Protection to the Full Body against Airborne Solid Particulates
Type 6-B Offering Limited Protective Performance against Liquid Chemicals
are tested and evaluated according to
EN 14126:2003/AC:2004, EN ISO 13982-1:2004/A1:2010, EN 13034:2005+A1:2009, EN 1149-5:2018
Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 3, it is approved that the product meets the requirements of the regulation.
Product Definition
Brand Name: MICROSAFE, Model : PREMIER CA-306
Resistance to penetration by contaminated liquids: Class 2
Resistance to penetration by contaminated solid particles: Class 2
Here by 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 V
Ongoing successful performance in fulfilment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on Annex V (Module C2) or Annex X (Module D) 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 harmonised standard affecting the essential health and safety requirements
CE 2163
Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director
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
Tek Kullanımlık ve Yeniden Kullanılabilir Medikal Ürünleri İmalatı ve Satışı
Release Date / Yayın Tarihi
22.06.2020
Last Issue Date / Son Basım Tarihi
22.06.2020
Expiry Date / Geçerlilik Tarihi
21.06.2021
Period Exp. Date / Bitiş Tarihi
21.06.2023
DIRECTOR
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QUALITY MANAGEMENT


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