



# CERTIFICATE

## PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

YUKARI DUDULLU MAH. BAYRAK CAD. NO:30 D:130  
ÜMRANİYE / İSTANBUL / TÜRKİYE

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

### ISO 9001:2015

*The Quality Management System is applicable to:*  
*Kalite Yönetim Sistemi:*

DESIGN, PRODUCTION, SALES, IMPORT AND EXPORT OF DISPOSABLE NON-STERILE AND  
STERILE PROTECTIVE OVERALLS, PROTECTIVE HAIR CAP, PATIENT AND DOCTOR  
PROTECTIVE APRON, STRETCHER COVER, FOOT COVER, PROTECTIVE MASK

TEK KULLANIMLIK NON-STERİL VE STERİL KORUYUCU TULUM, KORUYUCU SAÇ BONESİ,  
HASTA VE DOKTOR KORUYUCU ÖNLÜĞÜ, SEDYE ÖRTÜSÜ, AYAK KORUYUCU, KORUYUCU  
MASKE TASARIMI, ÜRETİMİ, SATIŞI, İTHALATI VE İHRACATI

Certificate Number: QMS-0102626  
Belge Numarası: QMS-0102626

Initial Certification Date: 17.12.2021  
İlk Belgelendirme Tarihi: 17.12.2021

Certification Period: 3 Years  
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 16.12.2022  
Belge Geçerlilik Tarihi: 16.12.2022



IQR Sertifikasyon Onayı

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA  
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com



# CERTIFICATE

## PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

YUKARI DUDULLU MAH. BAYRAK CAD. NO:30 D:130  
ÜMRANİYE / İSTANBUL / TÜRKİYE

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

### ISO 13485:2016

*Medical Devices-Quality Management System is applicable to:  
Tıbbi Cihazlar Kalite Yönetim Sistemi*

DESIGN, PRODUCTION, SALES, IMPORT AND EXPORT OF DISPOSABLE NON-STERILE AND  
STERILE PROTECTIVE OVERALLS, PROTECTIVE HAIR CAP, PATIENT AND DOCTOR  
PROTECTIVE APRON, STRETCHER COVER, FOOT COVER, PROTECTIVE MASK

TEK KULLANIMLIK NON-STERİL VE STERİL KORUYUCU TULUM, KORUYUCU SAÇ BONESİ,  
HASTA VE DOKTOR KORUYUCU ÖNLÜĞÜ, SEDYE ÖRTÜSÜ, AYAK KORUYUCU, KORUYUCU  
MASKE TASARIMI, ÜRETİMİ, SATIŞI, İTHALATI VE İHRACATI

Certificate Number: 2021/MDQMS/10570  
Belge Numarası: 2021/MDQMS/10570

Initial Certification Date: 17.12.2021  
İlk Belgelendirme Tarihi: 17.12.2021

Certification Period: 3 Years  
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 16.12.2022  
Belge Geçerlilik Tarihi: 16.12.2022



IQR Sertifikasyon Onayı

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA  
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com



## CATALOG 2022

Your reliable partner for personal protective equipment, coveralls, protective gowns, hoods, shoe covers, protective masks and bed sheets





## Gowns

Protective gowns and visitor gowns for **medical sector** to protect health professionals, patients and visitors against viruses and germs.

Also applicable in food industry, manufacturing, laboratories and pharmacies.

## Coveralls

Disposable protective suits offer protection for the **whole body** against microorganisms and hazardous substances in painting or, working with asbestos or in the food industry.

Disposable protective suits manufactured by PODIMA protect health and clothing.



## Hoods & Bonnet

Disposable hoods ensure multiple protections by open wounds during surgeries.

Additionally, disposable hoods avoid food to be contaminated by hair or dandruff in **food industry or gastronomy**.



## Shoe covers

Applicable in medical sector and food industry, shoe covers avoid contamination and offer protection both for **Ground** (e.g. sandy shoes on damp ground) and **shoes** (e.g. protection from dust or paints during).



## CONTENTS

Gowns	4
Coveralls	14
Hoods & Bonnet	20
Shoe Covers Masks	26
Bed Sheets & Covers	32
Certificates	35
Productions Process	38
	39



# Gowns

---

FOR THE SAFETY OF ALL  
IN HEALT CARE FACILITIES





Colors



## ISOLATION DISPOSABLE VISITOR GOWN

Protective gowns used for minimal risk situations. Slightly barrier to small of fluid penetration. The gowns are breathable and guarantees a easy to wear.

	XS	S	M	L	XL	2XL	3XL	4XL	Average
A	47	48	49	50	51	52	53	54	+/-2cm
B	58	59	60	61	62	63	64	65	+/-2cm
C	105	110	115	120	125	130	135	140	+/-2cm
D	130	135	140	145	150	155	160	165	+/-2cm

## SERVICES



## DETAILS

- Level 1
- CE Certified
- Elastic Cuffs
- Two laced belt sytem for good fit secure.
- Adjustable Velcro tape on neck
- 100% SS / SMS
- 20 – 80 Gsm
- White, Yellow, Blue, Green Color Options
- Laboratory Tested
- High Strength
- Optional Static / Antistatic
- Optional Sterile / Non Sterile

For more information, please refer to the data sheets.

DISPOSABLE VISITOR  
GOWN

**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



TYPE 6-B

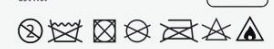


MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





Colors



## SMS SURGICAL GOWN

SMS Surgical Protective gowns are made of soft "spunbond + meltblown + spunbond" fabriks The gown is robust, breathable and guarantees a high barrier effect against dangerous particles and liquid splashes.

	XS	S	M	L	XL	2XL	3XL	4XL	Average
A	47	48	49	50	51	52	53	54	+/-2cm
B	58	59	60	61	62	63	64	65	+/-2cm
C	105	110	115	120	125	130	135	140	+/-2cm
D	130	135	140	145	150	155	160	165	+/-2cm

## SERVICES



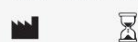
## DETAILS

- Fabric: SMS
- Weight : 25 – 80 Gsm
- Liquid Resistant
- Breathable
- White knitted cuffs
- High wearing comfort
- Protection against blood and other body fluids
- Bacteria barrier protection, antiallergic protection.
- Optional Static / Antistatic
- Optional Sterile / Non Sterile

For more information, please refer to the data sheets.

DISPOSABLE  
SURGICAL GOWN  
**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



MANUFACTURER:

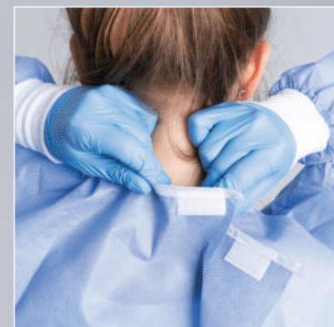
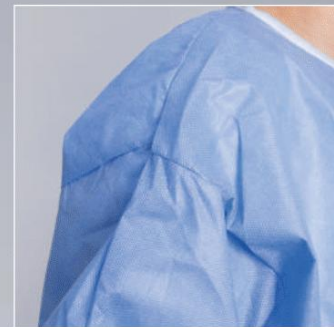
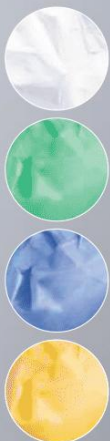
IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY



Colors



## SURGICAL GOWN (SMMS)

Podima Surgical gowns made of comfortable non-woven fabric and contains particularly high-quality four layers of SMMS (spunbond + meltblown + meltblown + spunbond) fabric.

This protective clothing is for single use as a protective gown or surgical gown. It is also used to protect health professionals, staff and visitors against contamination with bacteria and viruses in hospitals, operating theaters, laboratories or other medical facilities, food industry, dusty environments and working conditions where are contacts with asbestos and non-hazardous chemicals.



	XS	S	M	L	XL	2XL	3XL	4XL	Average
A	47	48	49	50	51	52	53	54	+/-2cm
B	58	59	60	61	62	63	64	65	+/-2cm
C	105	110	115	120	125	130	140	140	+/-2cm
D	130	135	140	145	150	155	160	165	+/-2cm

### DETAILS

- Material : Polypropylene Non woven (PP)
- Weight : Gr: 30 – 80 gsm
- Liquid resistant
- Breathable
- White knitted cuffs
- High wearing comfort
- Optional Static / Antistatic
- Optional Sterile / Non Sterile
- Protection against blood and other body fluids
- Bacteria barrier protection, antiallergic protection

For more information, please refer to the data sheets.

DISPOSABLE SURGICAL  
GOWN (SMMS)  
**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY

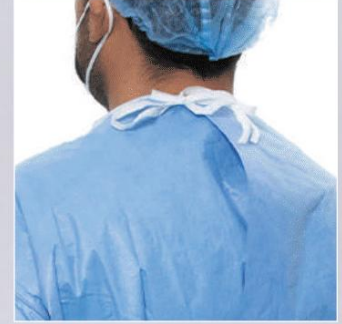
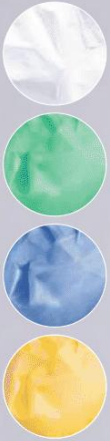


### SERVICES





Colors



## SSMLMS + PE LAMINATED

Protective gown is made of high protect fabric and breathable material to use in clinical, surgical and laboratory environments to protect health professionals and staff. Used in high risk situations. Prevents all fluid penetration. It contains ribbon cuffs for better freedom of movement. It is also comfortable and easy to tie at the waist and collar at the back.

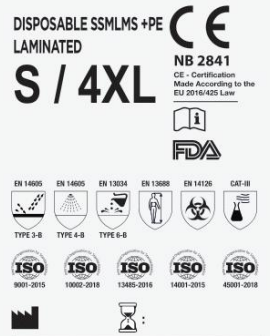
(Optional: Collar with Velcro fastener)

	XS	S	M	L	XL	2XL	3XL	4XL	Average
A	47	48	49	50	51	52	53	54	+/-2cm
B	58	59	60	61	62	63	64	65	+/-2cm
C	105	110	115	120	125	130	135	140	+/-2cm
D	130	135	140	145	150	155	160	165	+/-2cm

## DETAILS

- TYPE: PB-3B / PB-4B / PB-6B AAMI
- Material: 6 layers SSMLMS
- Weight: 33 gsm / m<sup>2</sup> SSMLMS + 22g / m<sup>2</sup> medical PE film (three-layer, breathable)
- Stitch type: Overlock 4-5 threads, welded (Optional: Ultrasonic seam)
- Highest possible protection class :

For more information, please refer to the data sheets.



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY

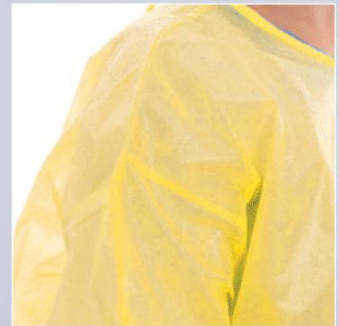
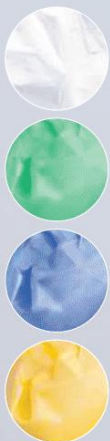


## SERVICES





Colors



## EXAMINATION GOWN: PP + PE GOWN

Examination gowns are especially suitable for sensitive areas such as operating theaters. It is particularly characterized by its tightness, therefore is also certified to EN14126.

	XS	S	M	L	XL	2XL	3XL	4XL	Average
A	47	48	49	50	51	52	53	54	+/-2cm
B	58	59	60	61	62	63	64	65	+/-2cm
C	105	110	115	120	125	130	135	140	+/-2cm
D	130	135	140	145	150	155	160	165	+/-2cm

## SERVICES



## DETAILS

- TYPE: PB-3B / PB-4B / PB-6B AAMI
  - Colours: blue & yellow
  - Weight: 32-80 gsm
  - Blood and virus density
  - Material: PP fabric + PE (MRSA protection)
  - PP (Polypropylen) non-woven fabric with PE (polyethylene) coating (approx. 36g)
  - Coating: fully coated, 100% PE-laminated to protect against splashes and infectious agents (Optional: can also be ordered as partially coated)
- For more information, please refer to the data sheets.**

DISPOSABLE  
EXAMINATION GOWN:  
PP + PE GOWN  
**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



MANUFACTURER:

IMPORTER:

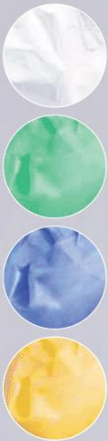
Barcode No:  
Lot No:

MADE IN  
TURKEY





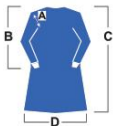
Colors



## DISPOSABLE REINFORCED GOWN

Our Level 3 gowns provide a high level of protection. Manufactured using the ultrasonic sewing method, the apron features an adjustable neck fastening, fastening straps at the back and sleeve cuffs. Produced for use in hospitals, operating rooms and health institutions.

Resistant to moisture and bacteria penetration. Puncture, tear and abrasion resistant. Resistant to toxic substances Free of lint and dust.



	XS	S	M	L	XL	2XL	3XL	4XL	Average
A	47	48	49	50	51	52	53	54	+/-2cm
B	58	59	60	61	62	63	64	65	+/-2cm
C	105	110	115	120	125	130	135	140	+/-2cm
D	130	135	140	145	150	155	160	165	+/-2cm

### DETAILS

- Fabric : Polypropylene (PP) + PE Optional SMMS + PE
- Weight : 35 – 80 Gsm
- Highly comfortable to wear
- Liquid repellent
- Breathable
- Protection against blood and other body fluids
- Protective features: antistatic protection, optional ultrasonic sealing.
- Bacteria barrier protection, anti-allergic protection
- Optional Static / Antistatic
- Optional Sterile / Non Sterile

For more information, please refer to the data sheets.

DISPOSABLE  
REINFORCED GOWN  
**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY

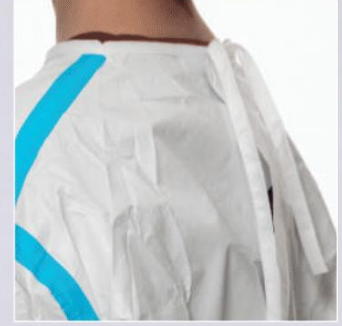


### SERVICES



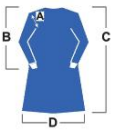


Colors



## PP+PE HIGH PROTECTION THERMOBAND STRIPED GOWN

High Protective gown is made of light and breathable material to use in clinical and laboratory environments to protect health professionals, staff and visitors against the transmission of microorganisms and body fluids. It contains ribbon cuffs for freedom of movement. It is also comfortable and easy to tie at the waist and collar at the back. (Optional: Collar with Velcro fastener)



	XS	S	M	L	XL	2XL	3XL	4XL	Average
A	47	48	49	50	51	52	53	54	+/-2cm
B	58	59	60	61	62	63	64	65	+/-2cm
C	105	110	115	120	125	130	135	140	+/-2cm
D	130	135	140	145	150	155	160	165	+/-2cm

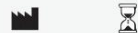
### DETAILS

- TYPE: PB-3B / PB-4B / PB - 5B / 6B AAMI
- Material: non woven, SSMMS-PE coated .
- Breathable. (three-layer, breathable)
- Weight: weight 33g / m<sup>2</sup> SSMMS + 22g / m<sup>2</sup> medical PE film
- Stitch type: Overlock 4-5 threads, welded
- Optional: Ultrasonic seam
- Optional: Static / Antistatic
- Highest possible protection class

For more information, please refer to the data sheets.

DISPOSABLE STRIPED GOWN  
**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY



### SERVICES






Colors

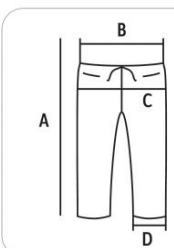


## THERMAL SET

Thermal jacket and trousers by PODIMA offers long-lasting warmth for the OP staff. With elastic band on the lower back, fits perfectly. The jacket is equipped with two pockets. Knitted cuffs.



	S	M	L	XL	2XL
A	73	75	77	79	81
B	55	57	59	61	63
C	68	70	72	73	74
D	31	32	33	34	35



	S	M	L	XL	2XL
A	98	100	102	104	106
B	34	36	38	40	42
C	53	55	57	59	61
D	20	21	22	23	24

## DETAILS

- Fabric: SS - SMS - SMMS
- Weight: 40 – 80 gsm
- Knitted Cuff and knitted neck collar
- Optional two or three pocket model
- Stitch type: Overlock 4-5 threads
- Optional Separate piece
- Optional Static / Antistatic
- Optional Sterile / Non Sterile

For more information, please refer to the data sheets.

DISPOSABLE THERMAL SET  
**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

IMPORTER:

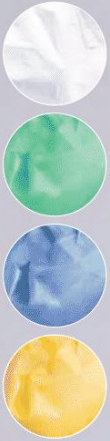
Barcode No:  
Lot No:

MADE IN  
TURKEY



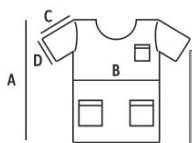


Colors

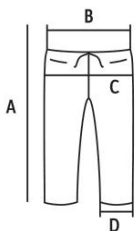


## V-NECK SET

V-neck set by PODIMA offers long-lasting warmth for the OP staff. The ja-cket is equipped with trousers.



	S	M	L	XL	2XL
A	73	75	77	79	81
B	53	55	57	59	61
C	20	21	22	23	24
D	18	18,5	19	19,5	20



	S	M	L	XL	2XL
A	98	100	102	104	106
B	34	36	38	40	42
C	53	55	57	59	61
D	20	21	22	23	24

## DETAILS

- Fabric: SS - SMS - SMMS
- Weight: 20 – 80 gsm
- Optional two or three pocket model
- Stitch type: Overlock 4-5 threads
- Optional Static / Antistatic
- Optional Sterile / Non Sterile
- Optional without pocket

For more information, please refer to the data sheets.

DISPOSABLE V-NECK SET

**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





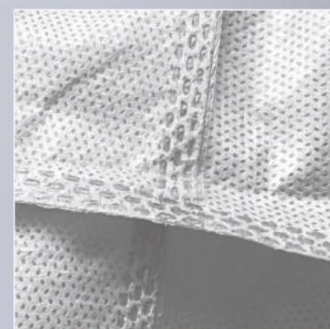
# Coveralls

---

FOR THE SAFETY OF ALL  
IN HEALT CARE FACILITIES

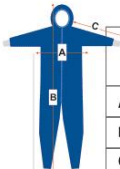


Colors



## COVERALL TYPE 3/4 ULTRASONIC

It is an economical solution for protection against limited chemical splashes such as paintspray applications. PPE directive Category III, Type 3/4 protection standard approved. The microporous material allows air to escape through the garment, but also provides protection from external hazards. Manufactured by ultrasonic sewing from laminated non-woven materials for Type 3 and Type 4 protection. Anti-static products can help reduce static buildup.

		SIZES	1 2 3 4 5 6 7							Average
			S	M	L	XL	2XL	3XL	4XL	
A	WAISTBAND	CM	50	52	54	56	58	60	62	+/-2cm
B	LENGTH	CM	188	190	192	194	196	198	200	+/-2cm
C	ARM LENGTH	CM	74	75	78	80	82	84	86	+/-2cm

### DETAILS

- Fabric: % 100 Spoonbond hotmelt Polyethylen % 54 + PP + %41 PE
- Weight : 55 – 80 gsm
- Stitch type: Overlock 4-5 threads
- Highly comfortable to wear, comfortable cut, but highly protective
- Elastic bands on sleeves, hood, legs and waist
- 2-way zipper with which it can be closed tightly
- Self-adhesive cover
- Elastic back and ankle areas to reduce the risk of skin contact
- Optional Static / Antistatic
- Optional Sterile / Non Sterile
- Optional Ultrasonic seam

For more information, please refer to the data sheets.

DISPOSABLE COVERALL

**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY

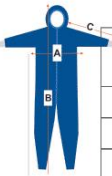


Colors



## COVERALL TYPE 3/4 THERMO BAND STRIPPED

Type 3/4 protective coveralls are characterized by its welded seams and thus offers even greater protection for liquids. This protective suits are suitable for the conditions in which one works with dangerous biological and chemical substances.

		SIZES		1	2	3	4	5	6	7	
				S	M	L	XL	2XL	3XL	4XL	Average
A	WAISTBAND	CM		50	52	54	56	58	60	62	+/-2cm
B	LENGTH	CM		188	190	192	194	196	198	200	+/-2cm
C	ARM LENGTH	CM		74	76	78	80	82	84	86	+/-2cm

### DETAILS

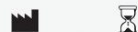
- Material: 100% spunbond hot melt polyethylene (54% PP, 41% PE, 55g)
- Breathable low-linting
- Elastic bands on sleeves, hood, legs and waist,
- Particularly high protection through welded seams
- 2-way zip, tightly closable with self-adhesive cover
- Optional Static / Antistatic
- Optional Sterile / Non sterile

For more information, please refer to the data sheets.

DISPOSABLE COVERALL

**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





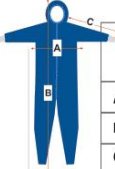
Colors



## COVERALL TYPE 5/6 B

Particle-tight and, to a limited extent, splash-tight, antistatic chemical protection suit / disposable coverall according to CE category III, type 5 + 6B

Can be used for medical purposes, construction, contaminated sites or asbestos remediation, spraying work in agriculture, ideal for industrial and automotive painters, etc.

		SIZES	1 2 3 4 5 6 7							
			S	M	L	XL	2XL	3XL	4XL	Average
A	WAISTBAND	CM	50	52	54	56	58	60	62	+/-2cm
B	LENGTH	CM	188	190	192	194	196	198	200	+/-2cm
C	ARM LENGTH	CM	74	76	78	80	82	84	86	+/-2cm

### DETAILS

- Material: 100% spunbond hot melt polyethylene (54% PP, 41% PE, 55g)
- Highly comfortable to wear, comfortable cut, but highly protective
- Elastic bands on sleeves, hood, legs and waist
- Breathable, lint-free, abrasion-resistant and antistatic
- Soft and lightly laminated microporous material
- 2-way zipper with which it can be closed tightly
- Self-adhesive cover
- Elastic back and ankle areas to reduce the risk of skin contact
- Optional Static / Antistatic
- Optional Sterile / Non sterile

For more information, please refer to the data sheets.

DISPOSABLE COVERALL

**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



MANUFACTURER:

IMPORTER:

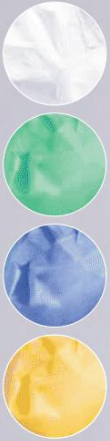
Barcode No:  
Lot No:

MADE IN  
TURKEY



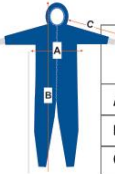


Colors



## COVERALL SS

Our overalls, which are produced for use in medical fields or as personal protective equipment, are produced from SS fabric, a type of non-woven fiber fabric that does not cause discomfort easily, is durable, breathable and water resistant. The fabrics used in our products are 100% (PP), silicone free and allergy free.

		SIZES		1	2	3	4	5	6	7	
				S	M	L	XL	2XL	3XL	4XL	Average
A	WAISTBAND	CM		50	52	54	56	58	60	62	+/-2cm
B	LENGTH	CM		188	190	192	194	196	198	200	+/-2cm
C	ARM LENGTH	CM		74	76	78	80	82	84	86	+/-2cm

## DETAILS

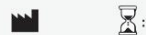
- Material: 100% spunbond
- Weight 20-80 gsm
- Highly comfortable to wear, comfortable cut, but highly protective
- Elastic bands on sleeves, hood, legs and waist
- Breathable, lint-free, abrasion-resistant and antistatic
- Soft and lightly laminated microporous material
- 2-way zipper with which it can be closed tightly
- Self-adhesive cover
- Elastic back and ankle areas to reduce the risk of skin contact

For more information, please refer to the data sheets.

DISPOSABLE COVERALL

**S / 4XL**

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY







# Hoods & Bonnet

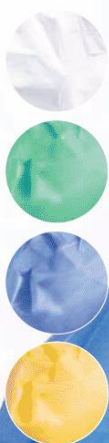
---

FOR THE SAFETY OF ALL  
IN HEALT CARE FACILITIES





#### Colors



## BARRET HOOD

Breathable, dustproof disposable SS cap. Selected SS fleece, environ-mentally- and skin-friendly. Effective protection against dust, fine dust, low-risk liquids and limited spraying. Dust and flake-proof, effectively reduces the amount of dust on a human body. Ideal for hygiene, labora-tory, industrial, examination and care areas.

## SERVICES



## DETAILS

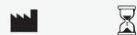
- Fabris : SS
- Weight : 10 - 12 gr
- Double stich
- Anti\_allergic.
- Gimped double elas\_c band.
- Air-permeable.
- Size: 40 x 45 cm / 52 x 52 cm / 40 x 45 cm

For more information, please refer to the data sheets.

DISPOSABLE BONNET



CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

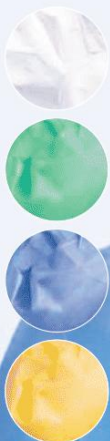
IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY



Colors



Packaging



## ASTRO HOOD

Disposable surgical cap in Astroform, non-woven SMMS non-sterile. Light material protects from contamination. It is made of light, air-per-meable polypropylene spunbond (PP). The size is individually adjustable. Virus-proof according to.

## SERVICES



## DETAILS

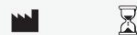
- Fabris : Optional SS - SMS - SMMS
- Weight : 20 - 60 gr

For more information, please refer to the data sheets.

## DISPOSABLE ASTRO HOOD



CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





#### Colors



## OPERATION BONNET

They are adjustable, lace-up caps with high permeability protection, especially for operating rooms.

#### Product usage areas

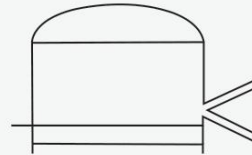
Hospital  
Medical industry  
Health Industry  
Beauty industry  
Pharmaceutical industry

## SERVICES



## DETAILS

- Fabris : Optional SS - SMS - SMMS
- Weight : 20 - 60 gr
- Color Optional



- Height : 20 cm
- Diameter : 30 cm

For more information, please refer to the data sheets.

## DISPOSABLE OPERATION BONNET



CE - Certification  
Made According to the  
EU (2016/425) Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





#### Colors



## SURGICAL HOODS WITH TIES

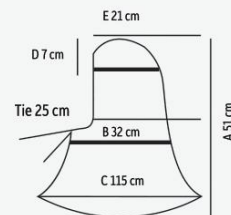
Lightweight and comfortable, our hood provides complete head, neck and shoulder coverage. Adjustable back ties allow for a personalized fit.

### SERVICES



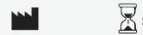
### DETAILS

- 100% SS/SMS Non-Woven
- 30-50 gsm
- Disposable
- Various colors available
- Comfortable



For more information, please refer to the data sheets.

### DISPOSABLE SURGICAL HOODS WITH TIES



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





Colors



## SURGICAL PP+PE LONG HOOD

Lightweight and comfortable, our hood provides complete head, neck and shoulder coverage. Adjustable back ties allow for a personalized fit.

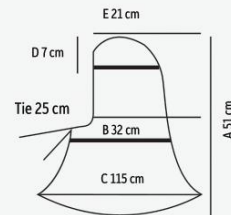
Extra long PP + PE maximum coverage  
Light weighted  
Ergonomic design & perfect fit egths  
Providing protection for the neck and shoulder area

## SERVICES



## DETAILS

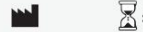
- 100% PP+PE Non-Woven
- 30-60 gsm
- Disposable
- Various colors available
- Comfortable



For more information, please refer to the data sheets.

DISPOSABLE SURGICAL  
PP+PE LONG HOOD

CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





# Shoe Covers

---

FOR THE SAFETY OF ALL  
IN HEALT CARE FACILITIES





Colors



## SHOE COVER SIMPLE

Liquid-resistant PE overshoes by PODİMA are ideal for clean rooms or areas that are particularly dirty. Thanks to the incorporated latex rubber, overshoes sit perfectly on feet and close tightly around ankles. With thicker materials, these overshoes are particularly easy to wear and do not tear quickly.

## SERVICES



## DETAILS

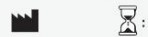
- Reinforced double elastic band, liquid proof, non-slip, tear-proof.
- Rope stitch technology is used to avoid.
- Shoe-cover ladders.
- Suitable for all shoe sizes.
- Produced in automatic machines without being touched.
- Compressed vacuum packaging
- Thickness : 9 micron – 20 Mivron optional
- Sizes Optional: 13 X 40 cm / 14 x 40 / 15 x 40 / 16 x 40

For more information, please refer to the data sheets.

DISPOSABLE SHOE  
COVER SIMPLE



CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY



Colors



## THERMO BAND STRIPED LONG BOOT COVER

Complements our foot cover and provides additional protection against infectious viruses. The heat-sealed tape on the seams prevents leakage and makes it the perfect accessory for our jumpsuit. Wear-resistant non-slip premium quality sole. Ergonomic construction provides ease of use and better fit. Elastic band and laces on the upper provide extra coverage.

### SERVICES



### DETAILS

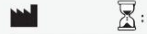
- Fabric: PP+PE(LAMINATED) + Thermoband
- Weight: 50-80 gsm
- Optional Static / Antistatic
- Optional Sterile / Non sterile

For more information, please refer to the data sheets.

### DISPOSABLE THERMO BAND STRIPED LONG BOOT COVER



CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





## BOOT COVER

Overshoes with type 5/6 are made of 100% polyethylene and have a unit size, so these overshoes fit everyone. With the light weight of 21 gr you won't even feel them. At the same time, they offer a high level of breathability due to air and watervapor permeability. They are made of materials repellent to water-based liquids and spray mist and are antistatic in accordance with EN1149-1. Elasticity at the ankle allows one to put on the shoes easily.

## SERVICES



## DETAILS

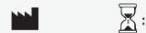
- Weight : 40 – 70 gsm
- Fabric: PP+PE(LAMINATED)
- High barrier against particles and fibers
- Silicone-free
- Elastic at the ankles
- Optional Static / Antistatic
- Optional Sterile / Non sterile

For more information, please refer to the data sheets.

## DISPOSABLE BOOT COVER



CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





## LONG NYLON BOOT COVER

Made of P.E Nylon 120 micron, tear-proof, non-slip, waterproof double bottomed double elastic, it can be pulled up to the knee. It does not contain carcinogenic substances, it is 100% antibacterial. Rubber double tire Liquid-proof, non-slip, tear-proof Suitable for all shoe sizes. Apart from hospitals and laboratories, it can be easily used in areas such as farms, agriculture, factories, slaughterhouses and car washes.

### SERVICES



### DETAILS

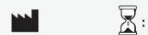
- Size: 50 x 40 cm
- Thickness 120 micron
- Material: P.E Nylon 120 micron

For more information, please refer to the data sheets.

DISPOSABLE LONG  
NYLON BOOT COVER



CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





## SHORT OVERSHOE PP+PE

Overshoes complete our protective coverall and provide additional protection against infectious viruses. Laminated is microporous and its seams are hidden and do not permeate. Sewn from premium-light and easy-to-wear PP NON-WOVEN fabric Made of soft durable , breathable and water resistant fabric. They have non-slip soles, lace up and extra They come with elastic band at the top for protection.

### SERVICES



### DETAILS

- Fabric: PP+PE (LAMINATED)
- Weight: 40-80 gsm
- Color: White-Blue
- Optional: non slip velcro tape

For more information, please refer to the data sheets.

### DISPOSABLE SHORT OVERSHOE PP+PE



CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





# Masks

---

FOR THE SAFETY OF ALL  
IN HEALT CARE FACILITIES





## FFP2 MASKS

FFP2 Against solid and liquid particles, but excluding carcinogenic and radioactive substances, airborne biological substances from risk groups 2 and 3 and enzymes.

Masks are designed to protect against harmful substances, contamination, bacteria and viruses. It is the user's responsibility to determine the suitability of the masks and use them in accordance with the instructions. Lining of skin, friendly material, elastic holders for a perfect fit, it easily covers the mouth and nose area.

## SERVICES

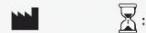


## DETAILS

- Material: 5 layers of fabric (3 layers non-woven fabric, and 2 layers meltblown filter layers)
- Filtration Efficiency: 95%≥ FFP2 Against solid and liquid particles, but excluding

For more information, please refer to the data sheets.

## DISPOSABLE FFP2 MASKS



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





## SURGICAL MASKS

### Surgical Face Mask face mask with Filter Type 2

- Material: Non-woven Spunbond + Meltblown + Spunbond
- Ultrasonic Seam
- Anti Allergic and Air Permeable
- EN 14683, Type II, High
- Filtration Efficiency BFE > 95%
- Covered Soft /
- Adjustable Nose Wire
- Single-use

### Surgical Face Mask face mask EU Type 1 | ASTM LVL 1

- 50 Pieces per package.
- 3 layers 3 plies.
- Does not feather.
- Full ultrasonic sewing.
- Does not contain latex.
- It is hygienic and hypoallergenic.
- It can be fixed to the nose part thanks to its wire part.
- It is sterilized with gamma rays.
- Thanks to its flexible and soft texture, it fits the face perfectly.
- Air-permeable.

## KID'S MASKS

### Face Mask face mask with Filter Type 2

- Material: Non-woven Spunbond + Meltblown + Spunbond
- Ultrasonic Seam
- Anti Allergic and Air Permeable
- EN 14683, Type II, High
- Filtration Efficiency BFE > 95%
- Covered Soft /
- Adjustable Nose Wire
- Single-use
- Optional: Colorud / Funny Design

## SERVICES





# Bed Sheets & Covers

---

FOR THE SAFETY OF ALL IN  
HEALTH CARE FACILITIES





Colors



## DISPOSABLE BED SHEET AND PILLOW

Bed Sheet Disposable Application. There is a different types of a hospital bed cover. Are ideal for any type of medical table, stretcher or patient bed. This includes hospital bed mattress cover for ambulance stretchers through to hospitality linens. They can be used in patient rooms in hospitals, clinics, or patient care facilities.

### SERVICES



### DETAILS

- Material: SS / SMS / PP+PE Non-woven
- Color: Optional White, Green, Blue
- Gram Weight: 20-80 gsm

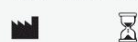
For more information, please refer to the data sheets.

DISPOSABLE  
BED SHEET  
AND PILLOW

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/435 Law



TYPE 6-B



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

MADE IN  
TURKEY





Colors



## BED COVER

Hygiene, fitted disposable sheets. Could be fitted all clinical beds, doctor examination rooms and other examinational beds. Fully covers any standard treatment could be also use Hotels, beauty centers, Sterilized, lightweight and portable.

## SERVICES



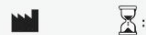
## DETAILS

- Fabric: SS / SMS non-woven fabric
- Color: Optional White, Green, Blue
- Gram Weight: 20-80 gsm
- Optional: steril / non steril
- Optional : PP + PE (laminated for waterproof)

For more information, please refer to the data sheets.

## DISPOSABLE DISPOSABLE BED SHEET AND PILLOW

**CE**  
NB 2841  
CE - Certification  
Made According to the  
EU 2016/425 Law



MANUFACTURER:

IMPORTER:

Barcode No:  
Lot No:

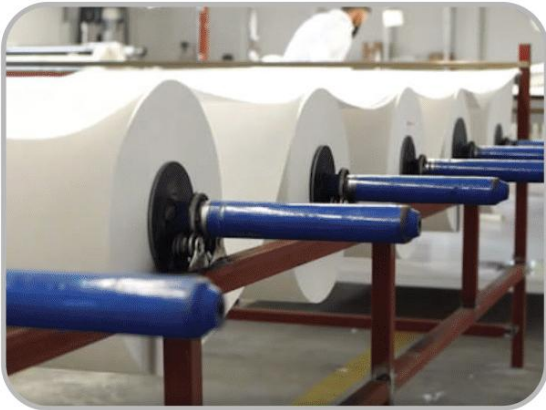
MADE IN  
TURKEY



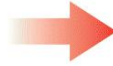
## OUR CERTIFICATES



## PRODUCTION PROCESS



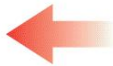
Raw Material



Tailoring



Sewing



Pressure Plastic Molding



Packaging



Delivery

## OUR SERVICES

### Fast delivery

Fast delivery from our Europe central warehouse with high capacity Turkey based production.

### EU certification

In order to be able to offer the best protection and the greatest security in everyday working life, we only sell certified products.

### Top products

We only carry tested, certified and high quality products.

### Fair prices

Thanks to strong partnerships and optimized business processes, we can pass on our products at fair prices.

## DECLARATION ON PRODUCT STANDARDS & SERVICES



### CATEGORY 3

Liquid-tight protective clothing:  
Full body or full protection suits against liquid chemicals



### EN 14605 TYPE PB 3-B

Liquid-tight protective clothing against liquid chemicals.  
EN 14605:2005 + A1:2009 TYP PB 3-B



### EN 14126

Protective clothing against infectious agents.  
EN 14126: 2003 + AC:2004



### EN 14605 TYPE PB 4-B

Spray-tight protective clothing against liquid chemicals.  
EN 14605:2005+A1:2009



### HOSPITAL



### INDUSTRY



### CORONA PROTECTION



### EN 13688

General requirement for protective clothing.  
EN ISO 13688:2013



### EN 13034 TYPE PB 6-B

Protective clothing against liquid chemicals with limited protection.  
EN 13034:2005 + A1:2009 TYP PB 6-B



### EN 13982 TYPE 5-B

Protective clothing against airborne solid particles  
EN ISO 13982-2:2004 TYP 5



### EN 1149

Protective clothing with electrostatic properties  
EN 1149-1:2006



### HYGIENE



### LABORATORY



### EMERGENCY

Contact: **PODiMA MEDİKAL VE TEKSTİL SAN. TIC. LTD. STİ.**

Şerifali Mah. Mevdudi Sk. No: 53/1, 34775  
Ümraniye İstanbul - Turkey

Tel: +90 216 784 07 93 / +90 216 314 93 16  
Email: [info@podimamedikal.com](mailto:info@podimamedikal.com)  
Web: [www.podimamedikal.com](http://www.podimamedikal.com)

Branch Office:  
Suvicom Media GmbH  
Kranhaus Süd  
In Zollhafen 24 50678  
Köln Germany

Phone: +49 221 65078065  
Email: [info@suvicom.de](mailto:info@suvicom.de)  
Web: [www.suvicom.de](http://www.suvicom.de)

**VALID** 2022 U.S. FDA Medical Device Establishment Registration

## PODIMA MEDIKAL VE TEKSTIL SANAYI TICARET LIMITED SIRKETI



### ESTABLISHMENT INFORMATION

Serifali Mahallesi Mevdudi Sokak No: 53 / 1  
Umraniye  
Istanbul, TR 34775

☎ 90-216-7840793

✉ [info@podimabilisim.com](mailto:info@podimabilisim.com)

🌐 <http://www.podimabilisim.com>



### U.S. AGENT AND OFFICIAL CORRESPONDENT

Registrar Corp  
144 Research Drive  
Hampton VA, USA 23666

☎ +1-757-224-0177

✉ [info@registrarcorp.com](mailto:info@registrarcorp.com)

🌐 [www.registrarcorp.com](http://www.registrarcorp.com)



Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by U.S. FDA.

## LISTINGS ON FILE WITH FDA

Device Name	Product Code	Status	Last Validated
Non-Surgical Isolation Gown	OEA	Valid	January 30, 2022
Suit, Surgical	FXO	Valid	January 30, 2022
Cap, Surgical	FYF	Valid	January 30, 2022

Device Name	Product Code	Status	Last Validated
Face Mask Per Enforcement Policy For Face Masks And Respirators During The Declared Public Health Emergency	QKR	Valid	January 30, 2022
Cover, Shoe, Operating-Room	FXP	Valid	January 30, 2022

# AB Tip İnceleme Sertifikası EU Type-Examination Certificate

**Belge No / Certificate No** : 63-20-08-R02  
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /**  
**Certification Date / Certificate Validity Date** : 05.04.2022-05.12.2025  
**Belge Geçerlilik Tarihi / Document Validity Period** : 5 Yıl/ 5 Years  
**Firma Unvanı ve Adresi /**  
**Company Name and Address** : PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.  
Yukarı Dudullu Mahallesi Bayrak Caddesi No: 30 Daire: 130  
Ümraniye 34775 İstanbul / Türkiye

**Ürün Adı /Modeller / Product Name / Models** : SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149  
**Direktifi / Directive** : 2016/425 REGULATION  
**Modülü/Kategori / Module / Category** : B MODÜLÜ/ KATEGORİ III  
MODULE B / CATEGORY III

**Teknik Değerlendirme Rapor No/**  
**Technical Evaluation Report No** : MNA 63-20-08-R02  
**Ürün Tipi / Product Type:**  
- EN ISO 13688:2013 Koruyucu giyecekler - Genel özellikler / Protective clothing - General requirements  
- EN 13034:2005+A1:2009 Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip PB 6-B) / Protective Clothing Against Liquid Chemicals (Type PB 6-B)  
- EN 14605:2005+A1:2009 Koruyucu Giyecekler - Sıvı Kimyasal Maddelere Karşı (Tip PB 3-B, Tip PB 4-B) / Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)  
- EN 14126:2003 Koruyucu Giyecekler - Patojen Organizmalara Karşı / Protective Clothing - Performance Requirements And Tests Methods For Protective Clothing Against Infective Agents

**Ürünün Malzeme Bilgisi / Product Material Information:** SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir./ SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model products are manufactured using coated fabric.

**Revizyon nedeni/ Reason for revision:** Kullanılan standartların tarihleri eklenmiştir. / Release date of standards has been added.

**Volkan AKIN**  
05.04.2022  
Karar Verici / Approver



**Okan AKEL**  
05.04.2022  
Şirket Müdürü / General manager



**ATTACHMENTS (63-20-08-R02)**

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

**Model :** SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	Type PB 3-B, Type PB 4-B, Type PB 6-B
Abrasion Resistance	1
Tear Resistance (Trapezoidal)	2
Tensile Strength	1
Puncture Resistance	1
Liquid Repellency	NaOH: 3, H <sub>2</sub> SO <sub>4</sub> : 3
Resistance To Penetration By Liquid	NaOH: 3, H <sub>2</sub> SO <sub>4</sub> : 3
Flex Cracking Resistance	1
Seam Strength	2
Permeation by Liquids	NaOH: 2
Wet Bacterial Penetration	1
Dry Microbial Penetration	1
Phi-X174 Bacteriophage	3

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

MARKING
<b>MANUFACTURER:</b> PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.
<b>PPE TYPE:</b> <ul style="list-style-type: none"><li>- EN ISO 13688:2013 Protective clothing - General requirements</li><li>- EN 13034:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 6-B)</li><li>- EN 14605:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)</li><li>- EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents</li></ul>
<b>MODEL:</b> SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149
<b>PRODUCT SIZE:</b> S, M, L, XL, 2XL, 3XL, 4XL

MNA Laboratuvarları San. Tic.Ltd .Şti

Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul

Tel: 0216 574 07 08 Faks: 0216 575 13 31 [www.mnalab.com](http://www.mnalab.com)

**ATTACHMENTS (63-20-08-R02)**

EN ISO 13688:2013

EN 14605:2005+ A1:2009 (Type 3-B, 4-B)

EN 14126:2003

EN 13034:2005+A1 (Type 6-B)



NB 2841

"Flammable material. Keep away from fire."  
"Do not re-use"

Type PB 3-B, Type PB 4-B, Type PB 6-B

MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

**PRODUCT PICTURES**

SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149

**DOCUMENTS IN THE TECHNICAL FILE**

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Technical Report

MNA Laboratuvarları San. Tic.Ltd .Şti

Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul

Tel: 0216 574 07 08 Faks: 0216 575 13 31 [www.mnalab.com](http://www.mnalab.com)

Report No : 63-20-08-R02

Report Date : 05.04.2022

Application No : 63-20-08

**1. COMPANY INFORMATION:**

PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

Yukarı Dudullu Mahallesi Bayrak Caddesi No: 30 Daire: 130 Ümraniye 34775 İstanbul / Türkiye

Tel: +905333221100

**2. PPE INFORMATION:**

Disposable non-sterile gown.

**3. PPE TYPE IDENTIFICATION**

EN ISO 13688:2013 Protective clothing - General requirements

EN 13034:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 6-B)

EN 14605:2005+A1:2009 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)

EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

**4. PPE PICTURES**



SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149

**5. PPE DIMENSIONS:**

SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model coverall has been found to be produced using S-M-L-XL-2XL-3XL-4XL size.

**6. PPE PRODUCT MATERIAL INFORMATION:**

The product is made of coated fabric.

## 7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- Protective clothing doesn't contain any sharp or hard edges or rough surfaces.
- Wearer donned and removed without any difficulties and clothing fits perfectly.
- The clothing doesn't obstruct blood circulation in any part of the body.
- The clothing design at armholes and crotch are appropriately proportioned and positioned.
- Sufficient closure arrangements given in the clothing and all the closures systems functioning properly.
- The coverage of protection zones of protective material is maintained during movements as extreme as it is anticipated a user would make.
- Wearer doesn't observe any difficulties while standing, sitting, walking, stair climbing, raising both hands above the head and bending over and picking up a small objects.
- While movements the protective material covers body area sufficiently.
- No difficulties in putting on and removing other items of PPE such as gloves and boots.

## 8. ANALYSIS AND EVALUATIONS:

### EN ISO 13688:2013

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
pH value	6,73	3,5 – 9,5	PASS

### EN 13034:2005+A1:2009, EN 14605:2005+A1:2009

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles >10 cycles >10 cycles >10 cycles	1 (>10 cycle)	PASS
Tear resistance	38,14	2 (>20N)	PASS
Tensile strength	41,99	1 (>30N)	PASS
Puncture resistance	6,20	1 (>5N)	PASS
Repellency to liquids	H2SO4: 98,4 NaOH: 98,6	3 (>90N) 3 (>90N)	PASS
Resistance to penetration by liquids	H2SO4: 0,9 NaOH: 0,7	3 (<1%) 3 (<1%)	PASS

Seam Strength	65,94	2 (>50N)	PASS
Resistance to penetration by jet of liquid (jet test)	0 cm <sup>2</sup>	3 times the maximum calibration stain	PASS
Flex cracking resistance	>500 cycles	1(>500 cycle)	PASS
Permeation	No leakage (%40 NaOH 30 min)	2 (>30 min)	PASS

#### EN 14126:2003

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage)	0 (PFU/ml) See the table below	3 (3,5 kPa)	PASS

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to wet bacterial penetration	Total penetration 0,19 % See the table below	1 (t≤15 min)	PASS

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Dry microbial penetration	2,04 log cfu	1 (2<log cfu≤3)	PASS

#### 9. DECISION PROPOSAL

Analysis and examinations SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model coded personal protective equipment; EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 14605:2005+A1:2009, EN 14126:2003 standards are evaluated. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

#### 10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports(M-2020-00451)
- User Instruction

Reason for revision : Relase dates of used standards has been added.

CONTROLLER : VOLKAN AKIN

SING :

DATE : 05.04.2021



Report No : 63-20-08-01-R01

Report Date : 05.04.2021

Application No : 63-20-08-01

**1. COMPANY INFORMATION:**

PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

Yukarı Dudullu Mahallesi Bayrak Caddesi No: 30 Daire: 130 Ümraniye 34775 İstanbul / Türkiye

Tel: +905333221100

**2. PPE INFORMATION:**

Disposable non-sterile gown.

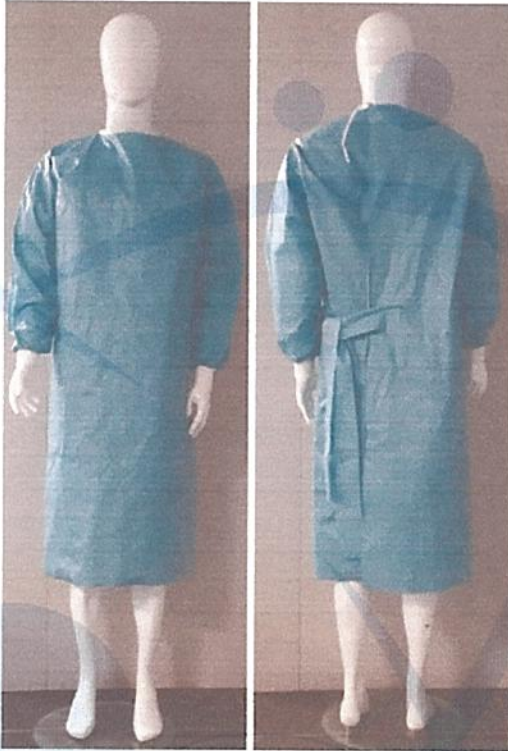
**3. PPE TYPE IDENTIFICATION**

EN 13688 Protective clothing - General requirements

EN 13034 Protective clothing against liquid chemicals (Type PB 6-B)

EN 14605+A1 Protective clothing against liquid chemicals (Type PB 3-B, Type PB 4-B)

EN 14126 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

**4. PPE PICTURES**

SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149

**5. PPE DIMENSIONS:**

SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model product has been found to be produced using S-M-L-XL-2XL-3XL-4XL size.

**CONFORMITY TO TYPE BASED ON INTERNAL  
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT  
CHECK AT RANDOM INTERVALS  
(MODULE C2, ANNEX VII) (63-20-08-01-R01)**

**6. PPE PRODUCT MATERIAL INFORMATION:**

The product is made of coated fabric.

**7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS**

- Protective clothing doesn't contain any sharp or hard edges or rough surfaces.
- Wearer donned and removed without any difficulties and clothing fits perfectly.
- The clothing doesn't obstruct blood circulation in any part of the body.
- The clothing design at armholes and crotch are appropriately proportioned and positioned.
- Sufficient closure arrangements given in the clothing and all the closures systems functioning properly.
- The coverage of protection zones of protective material is maintained during movements as extreme as it is anticipated a user would make.
- Wearer doesn't observe any difficulties while standing, sitting, walking, stair climbing, raising both hands above the head and bending over and picking up a small objects.
- While movements the protective material covers body area sufficiently.
- No difficulties in putting on and removing other items of PPE such as gloves and boots.

**8. ANALYSIS AND EVALUATIONS:**
**EN ISO 13688**

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
pH value	6,44	3,5 – 9,5	PASS

**EN 13034**

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles	1	PASS
Tear resistance	34,57 N	2	PASS
Tensile strength	37,32 N	1	PASS
Puncture resistance	5,87 N	1	PASS
Repellency to liquids	H2SO4: 99,2 NaOH: 99,1	3 3	PASS
Resistance to penetration by liquids	H2SO4: 0,3 NaOH: 0,6	3 3	PASS
Seam strength	50,78 N	2	PASS

**EN 14605+A1**

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to penetration by jet liquid (jet test)	0cm <sup>2</sup>	-	PASS
Permeation	No leakage (%40 NaOH 30 min)	2	PASS

**EN 14126**

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage)	3,5 kPa 0 (PFU/ml)	3	PASS
Resistance to wet bacterial penetration	%0,19	1	PASS
Resistance to penetration by biologically contaminant dust	2,02 (log cfu)	1	PASS

**9. DECISION PROPOSAL**

Analysis and examinations SUVICOM SV-140- SV-141 - SV-142 - SV-143 - SV-144 - SV-145 - SV-146 - SV-147 - SV-148 - SV-149 model coded personal protective equipment; EN 13688, EN 13034+A1, EN 14605+ A1, EN 14126 are evaluated. The homogeneity of the production was monitored at the performance levels determined as a result of the technical evaluations made within the scope of MODULE C2.

**10. ATTACHMENTS**

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports (M-2020-00629)
- User Instruction

Reason for revision : Company name and model name has been revised.

CONTROLLER : VOLKAN AKIN

SING : 

DATE : 05.04.2021



## EU DECLARATION OF CONFORMITY

in conformance to the European Economic Commission  
(EU) 2017/745 Medical Devices Regulation / Class I

This declaration of conformity is issued under the sole responsibility of PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. We hereby declare that the medical device specified below meet the provision of the Regulation (EU) 2017/745 for medical devices.

**MANUFACTURER:** PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.  
YUKARI DUDULLU MAH. BAYRAK CAD. NO: 30 / 130 ÜMRANIYE  
34775 İSTANBUL / TURKEY

**DESCRIPTION:** DISPOSABLE GOWN

**SPECIFICATION:** STERILE AND NON-STERILE

**ITEM NUMBERS:** SV-140 – SV-141 – SV-142 – SV-143 – SV-144 – SV-145 – SV-146 –  
SV-147 – SV-148 – SV-149

**TRADE MARK:**



**SUVICOM**

**DIRECTIVES:** European Regulation (EU) 2017/745 Medical Devices  
Regulation establishing technical requirements for  
medical devices, in effective wording.

**RELATED STANDARDS:** BASIC UDI-DI NUMBER:  
868305212SV-140SERIESQX

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

EN 13795-2:2019 Surgical Clothing And Drapes - Requirements And  
Test Methods - Part 2: Clean Air Suits

The manufacturer declares that the device was classified to class I  
by rule 1 according to Annex VIII of the above regulation. The  
conformity assessment was performed according to Annex II and III  
of the above regulation.

This medical device may be used safely for sanitary clothing.

**Issue Place and Date:**  
Istanbul, 20.01.2022

[www.podimamedikal.com](http://www.podimamedikal.com)

[info@podimamedikal.com](mailto:info@podimamedikal.com)



Name and Position of the authorized  
person: Mehmet Ali Özkan / Owner

**PODİMA MEDİKAL  
VE TEKSTİL SAN. TİC. LTD. ŞTİ.**  
Yukarı Dudullu Mah. Bayrak Cad. No: 30 D: 130  
Ümraniye / İSTANBUL Tic. Sic. No: 889545 - 0  
Sarıgazi V.D.: 730 037 5548

# SMMS SURGICAL GOWN



M E D İ K A L

**Product Name** SV-140  
**Category** CATEGORY III  
**N° Certificate** 63-20-08-R02  
**Date of Certificate** 05.04.2021-05.12.2025

## PRODUCT INFORMATION

**Color** : Blue  
**Packaging** : Single pack of 70 or 100 pcs.  
**Sizes** : S-4XL  
**Material** : 35 GR  
**Classification** : SMMS  
**Product Type** : SMMS Surgical Gown  
**Model Definition** : Disposable Gown

## DESCRIPTION SMMS SURGICAL GOWN

It is worn to protect the wearer against the patient during surgery or similar situations and to create a clean area in the environment. Spunbond, Meltblown, Meltblown, Spunbond (SMMS) is made of 100% PP non-woven fabric. Sweat absorbent, elastic cuffs made of 100% knit fabric are available. It is produced as sterile and non-sterile.

2 belts, velcro closure for neck, knitted cuffs for sleeves are available.

## IDENTIFICATION

### PPE Specification

Classification  
Abrasion Resistance  
Tear Resistance  
Tensile Strength  
Puncture Resistance  
Liquid Repellency  
Resistance to Liquid Penetration  
Flex Cracking Resistance  
Seam Strength  
Permeation by Liquids  
Wet Bacterial Penetration  
Dry Microbial Penetration  
Phi-x174 Bacteriophage

### Performance Levels

: Type PB 3-B, Type PB 4-B, Type PB 6-B  
: 1  
: 2  
: 1  
: 1  
: NaOH:3, H<sub>2</sub>SO<sub>4</sub>: 3  
: NaOH:3, H<sub>2</sub>SO<sub>4</sub>: 3  
: 1  
: 2  
: NaOH:2  
: 1  
: 1  
: 3



M E D İ K A L

PODIMA MEDİKAL VE TEKSTİL SAN.TİC. LTD. STİ.  
Y.DUDULLU MAH. BAYRAK CAD. NO:30 D:130  
UMRANIYE / İSTANBUL 34775

Product Name SV-140  
Category CATEGORY III  
N° Certificate 63-20-08-R02  
Date of Certificate 05.04.2021-05.12.2025

## IDENTIFICATION

- EN ISO 13688** Protective clothing – General requirements  
**EN 13034 + A1** Protective clothing Against Liquid Chemicals (Type PB-6-B)  
**EN 14126** Protective clothing Performance requirements and tests methods for protective clothing against infective agents  
**EN 14605+A1** Protective clothing Against Liquid Chemicals (Type 3B-4B)  
**ISO 9001: 2015** Quality Management System  
**ISO 10002: 2018** Customer Satisfaction Management System  
**ISO 13485: 2016** Medical Devices Management System  
**ISO 14001:2015** Environment Management System  
**ISO 45000:2018** Occupational and Safety Management System  
**FDA**

## WARNINGS

This is an indicative guide only. It must not be used as the only method for selecting the protective garment. Before using any protective clothing. The user must have read and understood all the instructions for use of the product. It is necessary to observe the legislation in force in each individual country. The selection of the most appropriate PPE or accessory depends on the particular situation and should only be made by a competent person who is aware of the specific working conditions and the limitations of PPE and accessories. It is the employer's responsibility to define the suitability of these products for the intended use. This information is subject to review at any time.

## SMMS SURGICAL GOWN

**PODiMA**

M E D İ K A L

Product Name SV-140  
Category CATEGORY III  
N° Certificate 63-20-08-R02  
Date of Certificate 05.04.2021-05.12.2025

### PACKAGING SIZE

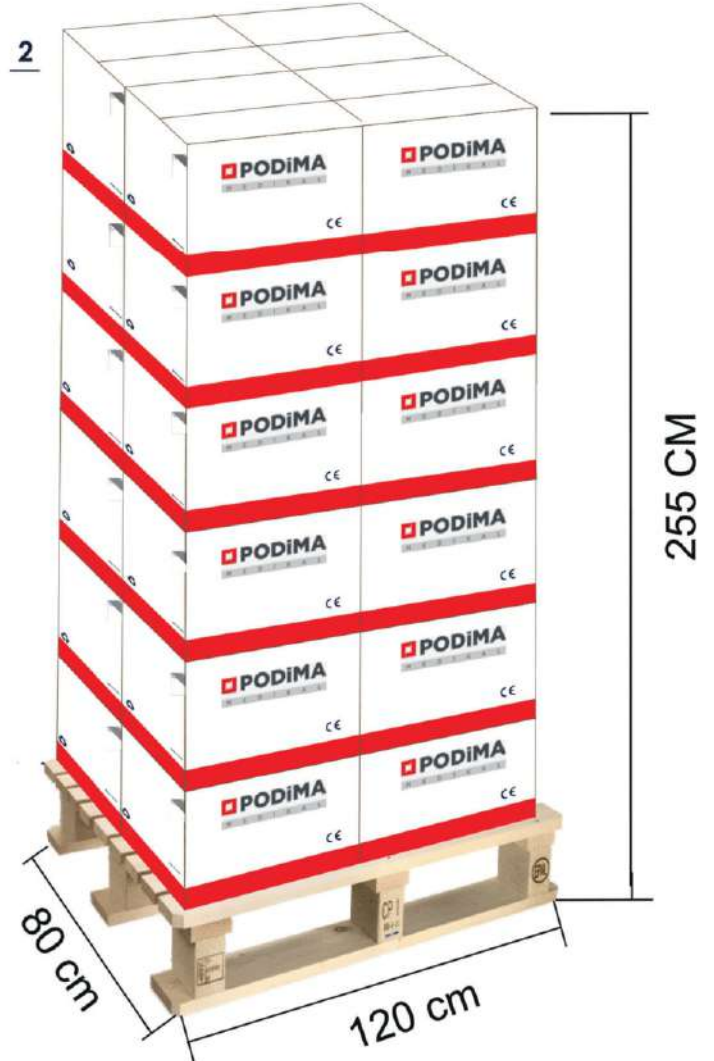
Width\*Depth\*Height

- 1) Carton Size **60\*40\*40 cm**  
2) Total Pallet Size **120\*80\*255 cm** (24 cartons in 1 pallet)

1 Container : 852 CTN (Without pallets)

1 Container : 768 CTN in 32 Pallets

- Single pack of 70 or 100 pcs



**PODiMA**

M E D İ K A L

PODİMA MEDİKAL VE TEKSTİL SAN.TİC. LTD. STİ.  
Y.DUDULLU MAH. BAYRAK CAD. NO:30 D:130  
UMRANIYE / İSTANBUL 34775