

LEVEL 4

STERILE TRIPLEX SURGICAL GOWN (S, M, L, XL, XXL, XXXL)

REF.NO:87.00X.01-88.00X.01-89.00X.01

PRODUCT DATASHEET

REVISION	REVISION DATE	REASON FOR REVISION
0	16.08.2023	-
1	24.08.2023	<i>Triplex surgical gown size chart has been added.</i>



PRODUCT DATASHEET
STERILE TRIPLEX SURGICAL GOWN – LEVEL 4

1) INFORMATION ABOUT THE PRODUCTS

Product Name: Sterile Triplex Surgical Gown (S, M, L, XL, XXL, XXXL)

510(k) Number: K230577

Trademark: Medcare Healthcare

Manufacturer: Medcare Sağlık Ürünleri San. ve Tic. A.Ş.

Intended Use: Sterile Triplex Surgical Gown (S, M, L, XL, XXL, XXXL) is a sterile, single-use surgical gown intended to be protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate materials. It has been tested and is classified as **Level 4** in the critical zones per **AAMI Standard PB70: Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use In Healthcare Facilities**.

REFERENCE CODE	PRODUCT NAME	SIZE
87.001.01	Sterile Triplex Surgical Gown with 1 hand towel	S
87.002.01	Sterile Triplex Surgical Gown with 1 hand towel	M
87.003.01	Sterile Triplex Surgical Gown with 1 hand towel	L
87.004.01	Sterile Triplex Surgical Gown with 1 hand towel	XL
87.005.01	Sterile Triplex Surgical Gown with 1 hand towel	XXL
87.006.01	Sterile Triplex Surgical Gown with 1 hand towel	XXXL
88.001.01	Sterile Triplex Surgical Gown with 2 hand towels	S
88.002.01	Sterile Triplex Surgical Gown with 2 hand towels	M
88.003.01	Sterile Triplex Surgical Gown with 2 hand towels	L
88.004.01	Sterile Triplex Surgical Gown with 2 hand towels	XL
88.005.01	Sterile Triplex Surgical Gown with 2 hand towels	XXL
88.006.01	Sterile Triplex Surgical Gown with 2 hand towels	XXXL
89.001.01	Sterile Triplex Surgical Gown	S
89.002.01	Sterile Triplex Surgical Gown	M
89.003.01	Sterile Triplex Surgical Gown	L
89.004.01	Sterile Triplex Surgical Gown	XL
89.005.01	Sterile Triplex Surgical Gown	XXL
89.006.01	Sterile Triplex Surgical Gown	XXXL



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2) PRODUCT IMAGES

Triplex Surgical Gown - Front



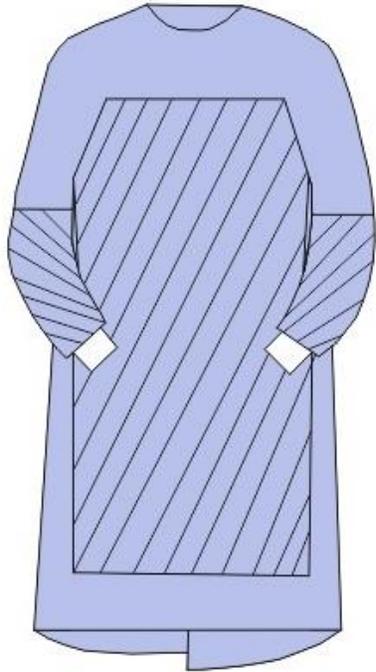
Triplex Surgical Gown - Back



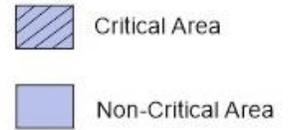
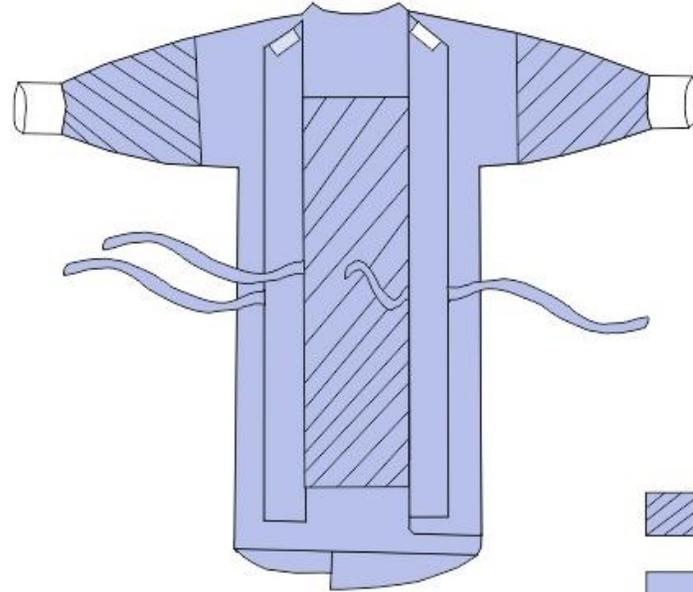
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3) TECHNICAL DRAWINGS

Triplex Surgical Gown Front Drawing

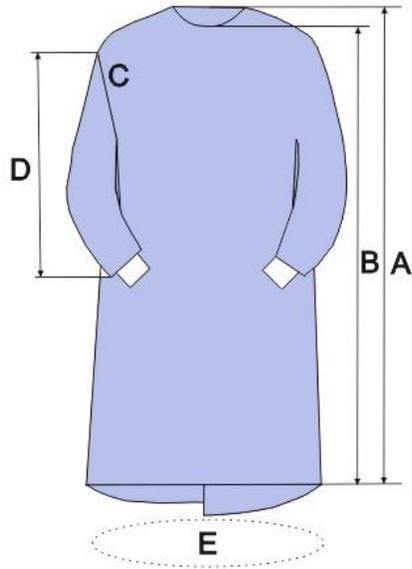


Triplex Surgical Gown Back Drawing



**PRODUCT DATASHEET
STERILE TRIPLEX SURGICAL GOWN – LEVEL 4**

4) TRIPLEX SURGICAL GOWN SIZES AND DIMENSIONS:



MEASUREMENT (inches)					
SIZE	A	B	C	D	E
S	43.31 (110 cm)	39.37 (100 cm)	11.02 (28 cm)	21.65 (55 cm)	55.12 (140 cm)
M	45.27 (115 cm)	41.33 (105 cm)	11.42 (29 cm)	22.83 (58 cm)	57.09 (145 cm)
L	50.0 (127 cm)	46.06 (117 cm)	11.42 (29 cm)	23.62 (60 cm)	59.05 (150 cm)
XL	53.14 (135 cm)	49.21 (125 cm)	12.59 (32 cm)	24.40 (62 cm)	61.02 (155 cm)
XXL	55.12 (140 cm)	51.18 (130 cm)	12.59 (32 cm)	25.19 (64 cm)	61.02 (155 cm)
XXXL	57.08 (145 cm)	53.14 (135 cm)	12.99 (33 cm)	25.98 (66 cm)	62.99 (160 cm)

TOLERANCES:- + 3%

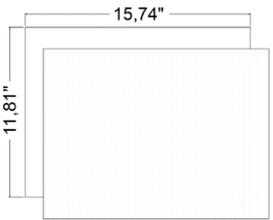
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5) COMPONENTS OF GOWN

NO	MATERIAL	MATERIAL TYPE	WEIGHT	DIMENSION	COLOUR
1	Fabric	Spunbond Polypropylene Nonwoven / PE Film / Spunbond Polypropylene Nonwoven	1.62 oz/yd ² (55 gr/m ²)	Size: S-M-L-XL-XXL-XXXL	Blue
2	Gown Belt	Spunbond Polypropylene Nonwoven / PE Film / Spunbond Polypropylene Nonwoven	1.62 oz/yd ² (55 gr/m ²)	4 pcs/gown Width:1.9 in (5 cm) Length:25.6 in (65 cm)	Blue
3	Elastic Cuff	98% Polyester + 2% Elastan	0.09 oz/yd ² (3,0 gr/m ²)	3.74 in (9,5 cm)	White
5	Velcro (Hook and Loop)	65% Polyester + 35% Polyethylene	-	Hook Width:0.78 in (2 cm) Hook Length:2.36 in (6 cm) Loop Width: 0.78 in (2 cm) Loop Length: 2.36 in (6 cm)	White

TOLERANCES:- + 3%

6) HAND TOWEL DESCRIPTION

Hand Towel Drawing			Picture of Hand Towel		
					
MATERIAL	MATERIAL TYPE	WEIGHT	DIMENSION	COLOUR	
Hand Towel	Scrim Absorbent Tissue Cellulose	1.92 oz/yd ² (65 gr/m ²) (+/-3%)	11.81 x 15.74 in (30x40 cm)	White	

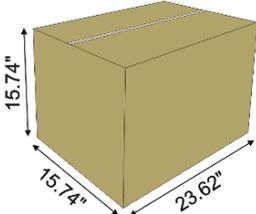
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7) PACKAGING	
Packing Quantity	1 (individual)
Sterilization Package Dimension	9.84x14.96 in (25x38 cm)
Quantity per box	30-40 pcs
Sterilization	EO (Ethylene Oxide)

Product Description	Product Code	Quantity Per Box
Sterile Triplex Surgical Gown with 1 hand towel, Small	87.001.01	40
Sterile Triplex Surgical Gown with 1 hand towel, Medium	87.002.01	40
Sterile Triplex Surgical Gown with 1 hand towel, Large	87.003.01	40
Sterile Triplex Surgical Gown with 1 hand towel, XLarge	87.004.01	40
Sterile Triplex Surgical Gown with 1 hand towel, XXXLarge	87.005.01	35
Sterile Triplex Surgical Gown with 1 hand towel, XXXLarge	87.006.01	30
Sterile Triplex Surgical Gown with 2 hand towels, Small	88.001.01	40
Sterile Triplex Surgical Gown with 2 hand towels, Medium	88.002.01	40
Sterile Triplex Surgical Gown with 2 hand towels, Large	88.003.01	40
Sterile Triplex Surgical Gown with 2 hand towels, XLarge	88.004.01	40
Sterile Triplex Surgical Gown with 2 hand towels, XXXLarge	88.005.01	35
Sterile Triplex Surgical Gown with 2 hand towels, XXXLarge	88.006.01	30
Sterile Triplex Surgical Gown, Small	89.001.01	40
Sterile Triplex Surgical Gown, Medium	89.002.01	40
Sterile Triplex Surgical Gown, Large	89.003.01	40
Sterile Triplex Surgical Gown, XLarge	89.004.01	40
Sterile Triplex Surgical Gown, XXXLarge	89.005.01	35
Sterile Triplex Surgical Gown, XXXLarge	89.006.01	30



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Production	Clean Room Conditions Medical Folding Sterilization Pouch, Size: 9.84x14.96 in (25x38 cm) Product/Box Label	
Labelling of product	Each unit <ul style="list-style-type: none"> - Product name - Reference code, - Lot number, - Size, - Production date, - Sterilization method, - Single use, - Manufacturer name and address 	
Packaging	<u>Pallet system</u>	<u>Carton Dimension</u>
	Height (in) -A	15.74 (40 cm)
	Width (in) - B	23.62 (60 cm)
	Length (in) - C	15.74 (40 cm)
	Emty Weight (lb)	~ 2.42 (1,1 kg)
		
Storage Instructions	<p>HANDLING AND STORAGE: Products must be stored in its original closed carton box, in a dry place. Sterile products must be used as soon as the package is opened in the operation room. Do not expose sterile products to humidity and direct heat or sunlight.</p> <p style="text-align: center;">Upper limit of temperature \downarrow 45°C</p>	