



PRODUCT DATASHEET
STERILE REINFORCED SURGICAL GOWN

Reference No	20.00X.01
Product Name	Sterile Reinforced Surgical Gown
Trademark	Medcare
Manufacturer	Medcare Sağlık Ürünleri San. Ve Tic. A.Ş.

Front side of reinforced surgical gown

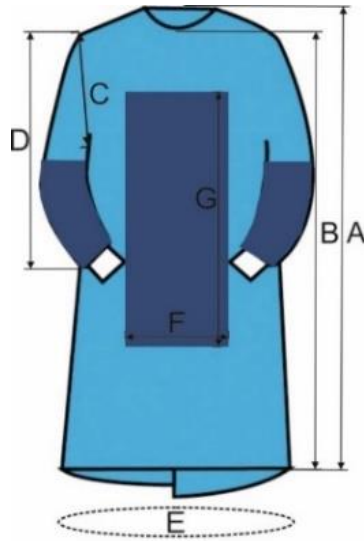


Back side of reinforced surgical gown



PRODUCT DATASHEET
STERILE REINFORCED SURGICAL GOWN
20.00X.01

1) PRODUCT



ITEM:1

Sterile Reinforced Surgical Gown

2) DETAILS OF PRODUCT COMPONENTS

ITEM	QTY	PRODUCT	FABRIC TYPE	DIMENSION	COLOUR
1	1	Sterile Reinforced Surgical Gown	Sms 43gr/m ² (+/-3)	XL-XXL	Blue

3) REINFORCED SURGICAL GOWN MEASUREMENT (cm)

SIZE	CODE	A	B	C	D	E	F	G
XL	20.004.01	135	125	32	62	150	50	100
XXL	20.005.01	140	130	32	64	155	50	100

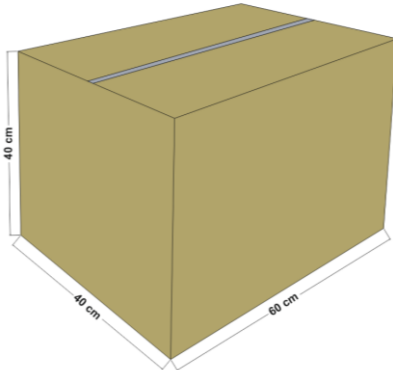
PRODUCT DATASHEET
STERILE REINFORCED SURGICAL GOWN
20.00X.01

4) GENERAL INFORMATION

Product Description	STERILE REINFORCED SURGICAL GOWN
Packing Quantity	XL-40 pcs XXL-35 pcs
Sterilization	EO (Ethylene Oxide)
Certificates	EC Certificate
	ISO 13485:2016
Standards	EN ISO 14971:2019
	EN 13795-1:2019
	EN ISO 11135:2014
	EN 556-1:2001
	EN ISO 15223-1:2016
	EN ISO 11737-1:2018
	EN ISO 11737-2:2020
	EN ISO 14644-1:2015
	EN ISO 14644-2:2015
	EN 17141:2020
	EN ISO 10993-1:2020
	EN ISO 10993-5:2009
	EN ISO 10993-7:2008
	EN ISO 10993-10:2010
	EN ISO 20417:2021
	EN ISO 11607-1:2020
	EN ISO 11607-2:2020
	EN 62366-1:2015
Instructions For Usage	This product can be used during the surgery operations. This product is disposable and it prevents the bacterial transfer between the medical team and the patient, reduces the occurring of possible contamination and infection between the patient and the medical team.
Expiry Date	3 years

PRODUCT DATASHEET
STERILE REINFORCED SURGICAL GOWN
20.00X.01

5) PACKAGING

All production				
Labelling of product	Clean Room Conditions,	Medical Folding,	Sterilization Bag,	Peelable label,
Each unit - Article number, - Lot number, - Manufacturer , - Production date, - Expiry date, - EO Sterilization, - Single use, - CE, - Other customer requests,				
Packaging				
<u>Pallet system</u>	<u>Carton</u>			
Height (cm) -A	40			
Width (cm) - B	60			
Length (cm) - C	40			
Storage Instructions	HANDLING AND STORAGE: Products are sterile and must be stored in its original closed carton box, in a dry place. The products must be used as soon as the package is opened in the operation room. Do not expose to humidity and direct heat or sunlight. 45°C Upper limit of temperature   % 70 % 10 Humidity Limitation			