



TECHNICAL DATA SHEET

STANDART SURGICAL GOWN

(EU) 2017/745 Annex XI-Part A Production Quality Assurance

Standart Surgical Gown

► Product Description	► Protective equipment used by doctors or nurses for surgical operations to prevent the possible risk of infection.
► Product Class	► (EU) 2017/745 Medical Device Regulation – Class Business Rule I
► Manufacturer's Location	► Tio Medikal 2/20 st. No.:53 (Begos 3. North Entrance, 35400 Buca OSB/Buca/İzmir)
► Purpose of usage	► These products are used as a protective barrier before, during and after surgical operations to prevent the risk of infection between patients, doctors, nurses or medical professionals in hospitals, clinics or intensive care units.

Quality

- Produced under ISO 13485:2016 and 13795-1 quality management standards.
- It has *CE certificate.

Bio-Compatibility

- Does not contain latex.
- Sterilised with ethylene oxide.

Related Standart

- ISO 13485:2016 Medical Devices Quality Management System
- 9001:2015 Quality Management System
- TS EN 13795 Surgical Clothing and Drapes
- TS EN ISO 11607-1:2017 Packaging for finally sterilised medical devices - Part 1: Rules for materials, sterile barrier systems and packaging systems /

Products are made in accordance with the relevant standard.

- TS EN ISO 11607-2:2017 Packaging of medical devices-Finally sterilised-
Part 2: Validation requirements for forming, sealing and joining processes/
Products are made in accordance with the relevant standard.

Shelf Life

- 3 years

Country of Origin

- This disposable Full Reinforced Surgical Gown is entirely
manufactured in Turkey



Shape 1. Standart Surgical Gown

1. Standart Surgical Gown Sizes

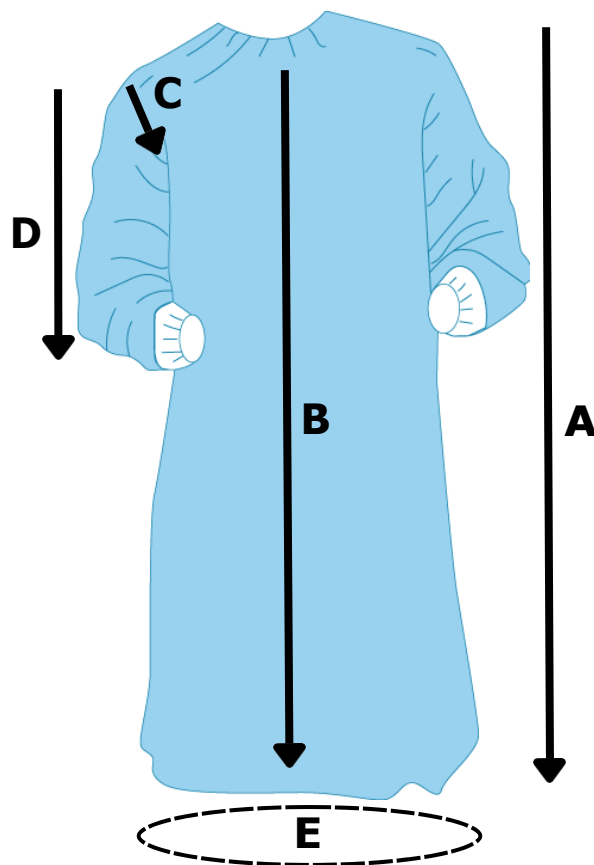


Figure 1. Standart Surgical Gown Technical Demonstration

Available Materials: SMS (Spunbond PP/Meltblown/Spunbond PP) 35 gr/m2

REF . CODES		DIMENSIONS (cm)					Pieces in Box	
		A	B	C	D	E	50×80×50	40×60×40
M	322.03.S01.01	115	105	29	58	145	100	50
L	323.03.S01.01	145	117	29	60	150	90	40
XL	324.03.S01.01	150	125	32	63	160	80	35
XXL	325.03.S01.01	155	125	32	63	160		

Tolerances: +3% (ALL SIZES ARE PRODUCED & CUSTOMISATION)

		EN 13795 requirements			
Characteristic	Test Method	High performance		Results	Main fabric
		Critical product area	Less critical product area		
Resistance to microbial penetration - Dry (CFU)	EN ISO 22612	Not required	<300	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Resistance to microbial penetration - Wet (I B)	EN ISO 22610	6,0	Not required	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Cleanliness - Microbial (CFU/100cm ²)	EN ISO 11737-1	<300	<300	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Cleanliness - Particulate matter (IPM)	EN ISO 9073-10	<3,5	<3,5	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Linting (Log ₁₀ (lint count))	EN ISO 9073-10	<4,0	<4,0	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Resistance to liquid penetration	EN 13795	≥ 100	≥ 10	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Bursting strength - dry	EN 13795	≥ 40	≥ 40	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Bursting strength - wet	EN 13795	Not required	≥ 40	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Tensile strength - dry	EN 13795	≥ 20	≥ 20	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Tensile strength - wet	EN 13795	Not required	≥ 20	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven

BIOCOMPATIBILITY

Biocompatibility studies has been done, and test results are given in the below table. Test results are within limits.

Table 31 Biocompatibility Study Documentation

<i>Test Name</i>	<i>Test Method</i>	<i>Test facility</i>	<i>Report No</i>	<i>Report Date</i>	<i>Result</i>
<i>Cytotoxicity</i>	ISO10993-5:2010	HACETTEPE UNIVERSITY	ARGEDS-2016/37	01.08.2016	<i>Confirmed</i>
<i>Sensitization</i>	ISO10993-10:2014	HACETTEPE UNIVERSITY	ARGEDS-2016/37	24.10.2016	<i>Confirmed</i>
<i>Skin Irritation</i>	ISO10993-10:2014	HACETTEPE UNIVERSITY	ARGEDS-2016/37	11.06.2016	<i>Confirmed</i>

Instruction for use:

1. The package of product shall be opened in sterile and aseptic conditions.
2. For a clean peel, open the package from the direction of the arrow slowly .
3. In order to wear the surgical gown, first of all put your hands into armholes.
4. Keep the gown away from your body and let it to be unfolded completely.
5. Slip your arms into sleeves.
6. The helping nurse will pull the gown over shoulders with touching only inside of the gown.
7. Make sure to overlap velcro bands on the neck part and arrange the distance.
8. Tie the inner belts of the gown.
9. Wear the gloves.
10. Hold the belt card and after pulling the outer belts from the card by the help of nurse, tie it together with the other outer belt on the left hand side.

	Do not use if package is damaged		Manufacturer		Single Use (Do not re-use)		Use by date
	Do not expose the product to sunlight.		Catalogue number		Consult instructions for use		Temperature Limitation
	Do not re-sterilize		Manufacturing Date		Sterilized using Ethyleneoxide and Single sterile barrier system		CE Marking
	Keep Dry		Batch Code		Caution		Medical device
	Unique device identifier						