TECHNICAL DATA SHEET
REINFORCED SURGICAL GOWN

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

Reinforced 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 manifectured in TURKEY

Figure 1. Reinforced Surgical Gown

1.Reinforced Surgical Gown Sizes

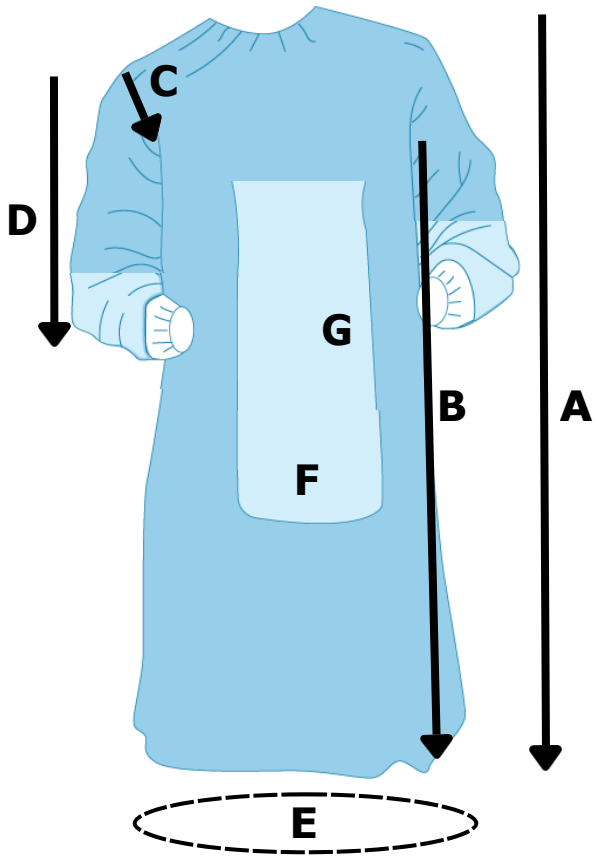

Figure 1. Reinforced Surgical Gown Technical Demonstration

Available Materials: SMS (Spunbond PP/Meltblown/Spunbond PP) 35 gr/m2 Reinforced fabric (PE+spunbond) 28gr

		DIMENSIONS (cm)							Pieces in Box	
	REF . CODES	A	B	C	D	E	F	G	50×80×50	40×60×40
M	312.03.R01.01	115	105	29	58	145	50	70	90	50
L	313.03.R01.01	145	117	29	60	150	50	70	80	40
XL	314.03.R01.01	150	125	35	63	160	50	85	75	35
XXL	315.03.R01.01	155	125	35	63	160	50	85	65	25

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/100cm²)	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 (Log10 (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

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

Table 31 Biocomtability Study Documentation

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

Instruction for use:

1. The package of product shall be opened in sterile and aceptic 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.	REF	Catalogue number		Consult instructions for use	30 °C 10 °C	Temperature Limitation
	Do not re-sterilize		Manufacturing Date	STERILE EO	Sterilized using Ethyleneoxide and Single sterile barier system	CE 2696	CE Marking
	Keep Dry	LOT	Batch Code		Caution	MD	Medical device
UDI	Unique device identifier						