TECHNICAL DATA SHEET
GOWN FOR CHEMOTHERAPHY

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

GOWN FOR CHEMOTHERAPHY

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, duringand 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.

Related Standart
- ISO 13485:2016 Medical Devices Quality Management System
- 9001:2015 Quality Management System
- TS EN 13795 Surgical Clothing and Drapes

Shelf Life
- 5 years

Country of Origin

- This disposable Chemotherapy gown is completely made in Turkey

Shape 1. Chemotherapy gown

1. Chemotherapy Gown Sizes

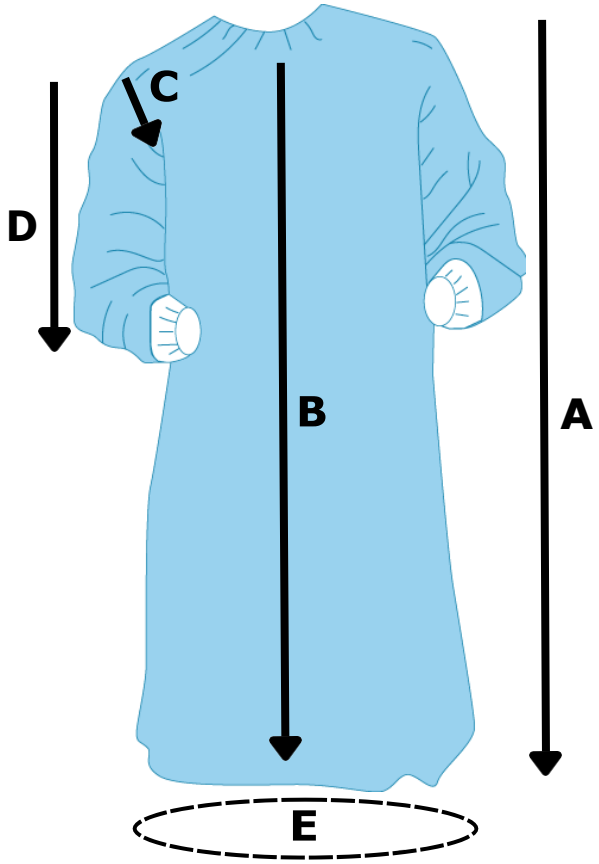

Figure 1. Chemotherapy Gown Technical Demonstration

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
XL	341.03.R01.02	135	125	32	63	160	90	40
XXL	342.03.R01.02	145	135	32	65	160	80	35

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

Characteristic	Test Method	EN 13795 requirements		Results	Main fabric
		High performance			
		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 (IB)	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. There are labels or marks on the drapes, which helps the user to follow the patient direction and unfolding directions.

	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		Sterilized using Ethyleneoxide and Single sterile barier system	CE	CE Marking
	Keep Dry	LOT	Batch Code		Caution	MD	Medical device
	Unique device identifier						