TECHNICAL DATA SHEET
SHORT FOR COLONOSCOPY

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

SHORT FOR COLONOSCOPY

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	It is used in colonoscopy procedures. Colonoscopy can be performed with disposable colonoscopy short without the need to fully open the hip area.

Quality
- Produced under ISO 13485:2016 and 13795-1 quality management standards.

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 short for colonoscopy is completely made in Turkey

Figure 1. Short For Colonoscopy

1. Short For Colonoscopy Sizes

Figure 1. Short For Colonoscopy Technical Demonstration

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

REF . CODES	DIMENSIONS (cm)		Pieces in Box	
			50×80×50	40×60×40
L 381.06.000.02	A	60 CM	90	40

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

BIOOCOMPATIBILITY

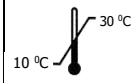
Biocompatability studies has been done, and test results are given in the below table. Test results are within limits.

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.
4. For the is incision film or adhesive tape on the drapes,first of all peel the paper carrier and fix the drape on the operational area of the patient. After then unfold the drape by following the directions.
5. Surgical drapes are ready for the operation, when they are completely unfolded.

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