

OPHTALMIC DRAPE

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

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

Quality

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

Bio-Compatibility

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

Related Standard

- 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 Packing for finally sterilised medical devices – Part 1: Rules for materials, sterile barrier system and packing systems / Products are made in accordance with the relevant standard.

Shelf Life

- 3 years

• Ophthalmic Drape with 2 Pouch Image

• Ophthalmic Drape with 2 Pouch Dimensions

	DIMENSIONS (CM)	NUMBER IN PACKAGE		
REF CODES	A	B	50X80X50	40X60X40
441.03.000.01	100	130	25	12
441.03.001.01	100	150	25	12

441.03.002.01	150	150	25	12
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Tolerances: $\pm 3\%$ (All sizes are produced & customisation)

Available Materials:

01 - SMS (Spunbond PP/Meltblown/Spunbond PP) , 35-43 gr/m2 + Incision Film (Fenestration is covered with polyurethane incision film) + PE (Pouch)

	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 - Surgical drape and gowns-Blue/white non woven - Surgical drape and gowns-Blue laminated nonwoven
Resistance to microbial penetration - Wet (I _B)	EN ISO 22610	6,0	Not required	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgical drape and gowns-Blue/white non woven - Surgical drape and gowns-Blue laminated nonwoven
Cleanliness - Microbial (CFU/100cm ²)	EN ISO 11737-1	<300	<300	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgical drape and gowns-Blue/white non woven - Surgical drape and gowns-Blue laminated nonwoven
Cleanliness - Particulate matter (IPM)	EN ISO 9073-10	<3,5	<3,5	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgical drape and gowns-Blue/white non woven - Surgical drape and gowns-Blue laminated nonwoven
Linting (Log10 lint count)	EN ISO 9073-10	<4,0	<4,0	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgical drape and gowns-Blue/white non woven - Surgical drape and gowns-Blue laminated nonwoven
Resistance to liquid penetration	EN 13795	≥ 100	≥ 10	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgical drape and gowns-Blue/white non woven - Surgical drape and gowns-Blue laminated nonwoven
Bursting strength - dry	EN 13795	≥ 40	≥ 40	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgical drape and gowns-Blue/white non woven - Surgical drape and gowns-Blue laminated nonwoven
Bursting strength - wet	EN 13795	Not required	≥ 40	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgical drape and gowns-Blue/white non woven - Surgical drape and gowns-Blue laminated nonwoven
Tensile strength - dry	EN 13795	≥ 20	≥ 20	Conformed	

					• SS Hydrophobic Spunbond • SS Hydrophylic Spunbond • Surgical drape and gowns-Blue/white non woven • Surgical drape and gowns-Blue laminated nonwoven
Tensile strength - wet	EN 13795	Not required	≥ 20	Conformed	• SS Hydrophobic Spunbond • SS Hydrophylic Spunbond • Surgical drape and gowns-Blue/white non woven • Surgical drape and gowns-Blue laminated nonwoven

Biocompatibility

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

<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>Sensitizasyon Sensitization</i>	ISO10993-10:2014	HACETTEPE UNIVERSITY	ARGEDS-2016/37	24.10.2016	<i>Confirmed</i>
<i>Cilt İritasyonu Skin Irritation</i>	ISO10993-10:2014	HACETTEPE UNIVERSITY	ARGEDS-2016/37	11.06.2016	<i>Confirmed</i>

Biocompatibility Study Documentation

Instruction for Use

- The package of products shall be opened in sterile and aseptical conditions.
- For a clean peel, open the package from the direction of the arrow slowly.
- There are labels or marks on the drapes, which helps the user to follow patient direction and unfolding directions.
- For the incision film or adhesive tape on the drapes, first of all peel the carrier and fix the drape on the operational area of the patient. After then unfold the drape by following the directions.
- Surgical drapes are ready for the operation, when they are completely unfolded.

Do not use if package is damaged	Manufacturer	Sterilized using ethyleneoxide and single sterile barrier system		Use by date
Do not expose the product to sunlight.	Manufacturing date	Caution		Temperature limitation
Keep dry	Catalogue number	Unique device identifier		Consult instructions for use
Do not re-sterilize	Batch code	Medical device	2696	CE marking
Single use (do not re-use)				