LASER EYE DRAPE

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

• Product Desription	• **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 standartds.
- It has CE certificate.

Bio-Compatibility

- Dos 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

- **Laser Eye Drape Image**

- **Laser Eye Drape Dimesions**

	DIMENSIONS (CM)	NUMBER IN PACKAGE		
REF CODES	**A**	**B**		**40X60X40**
451.04.000.01	**60**	**40**		**500**
451.04.001.01	**41**	**41**		**500**

Tolerances: ±3% (All sizes are produced & customisation)

Available Materials:
05 - PE TRANSPARENT 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 • Surgigal drape and gowns-Blue/white non woven • Surgigal 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 • Surgigal drape and gowns-Blue/white non woven • Surgigal drape and gowns-Blue laminated nonwoven
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 nonwoven
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 nonwoven
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 nonwoven
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 nonwoven
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 nonwoven
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 nonwoven
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 nonwoven
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 nonwoven

Biocompatibility

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

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*

Biocompatibility Study Documentation

Instruction for Use

- The package of products shall be opened in sterile and aceptic 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.
- Fort he is 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 fort he operatiıon, 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		Temperaturelimitation
	Keep dry		Catalogue number		Unique device identifier		Consult instructions for use
	Do not re-sterilize		Batch code		Medical device	2696	CE marking
	Simgle use (do not re-use)						