FLUOROSCOPY COVER

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

• Product Desription	**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 Sokak No:53 (Begos 3.Kuzey Giriş), 35400 Buca OSB / Buca / İzmir
• Purpose of Usage	• It is the sheath that covers the fluoroscopy device during the fluoroscopic imaging procedure to protect it from possible contamination of the device to patients from environmental conditions.

Quality

- Manufactured under ISO 13485:2016 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 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

- **Fluoroscopy Cover Image**

- **Fluoroscopy Cover Dimesions**

	DIMENSIONS(CM)		
REF CODES	**A**	**B**	**Ø**
219.10.000.01	**60**	**60**	**30**
219.10.001.01	**80**	**80**	**30**
219.10.002.01	**90**	**90**	**35**
219.10.003.01	**130**	**130**	**60**
219.10.004.01	**100**	**100**	**50**
219.10.005.01	**120**	**120**	**60**
219.10.006.01 219.10.007.01 219.10.008.01 219.10.009.01 219.10.010.01 219.10.011.01	**120**	**100**	**50**
219.10.015.01 219.10.016.01	**80**	**120**	**35**
	75	**75**	**30**
	75	**90**	**30**

90	**75**	**30**
90	**71**	**30**
265	**150**	**65**
250	**50**	**65**

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

Available Materials:
PE transparent 40-45 microns

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 covers, which helps the user to follow patient direction and unfolding directions.

	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)						