TECHNICAL DATA SHEET

FLUOROSCOPY COVER(Round)

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

FLUOROSCOPY COVER(Round)

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 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 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 Medical Devices Quality Management System
- 9001:2015 Quality Management System
- TS EN 13795 Surgical Clothing and Drapes
- TS EN ISO 11607-1:2017 Packaging for finally sterilised medical devices - Part 1: Rules for materials, sterile barrier systems and packaging systems / Products are made in accordance with the relevant standard.
- TS EN ISO 11607-2:2017 Packaging of medical devices-Finally sterilised-

Part 2: Validation requirements for forming, sealing and joining processes/ Products are made in accordance with the relevant standard.

Shelf Life

- 3 years

1.FLUOROSCOPY COVER(Round)Sizes

Figure 1. FLUOROSCOPY COVER(Round)

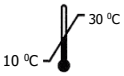
Available Materials: PE TRANSPARENT 40-45 microns

REF . CODES	DIMENSIONS (cm)
	Ø CM
219.10.00X.01	80

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

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.		Catalogue number		Consult instructions for use		Temperature Limitation
	Do not re-sterilize		Manufacturing Date		Sterilized using Ethyleneoxide and Single sterile barier system	 2696	CE Marking
	Keep Dry		Batch Code		Caution		Medical device
	Unique device identifier						