

TECHNICAL DATA SHEET

CAMERA COVER with Ring

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

➤ 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 Sokak No:53 (Begos 3.Kuzey Giriş), 35400 Buca OSB / Buca / İzmir
➤ Purpose of Usage	➤ It is the sheath used to prevent the camera used to view the internal organs of the patient from contacting the internal organs of the patient and to protect against the risk of contamination.

Quality

- Manufactured under ISO 13485:2016 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 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

1. Camera Cover with Ring Image



REF CODES	DIMENSIONS(CM)	
	A	B
251.11.000.01	250	14
211.10.001.01	275	13
211.10.002.01	250	15
211.10.003.01	300	15
211.10.004.01	300	18
211.10.005.01	250	18
211.10.006.01	245	18
211.10.007.01	75	35

Tolerances: $\pm 3\%$ (All sizes are produced & customisation)

Available Materials:

Polyethilene 50 micron

Instruction for Use

1. The package of products shall be opened in sterile and aseptical conditions.
2. For a clean peel, open the package from the direction of the arrow slowly.
3. 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		Temperature limitation
	Keep dry		Catalogue number		Unique device identifier		Consult instructions for use
	Do not re-sterilize		Batch code		Medical device		CE marking
	Single use (do not re-use)						