

PROBE COVER

(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 a sheath used to protect the patient against possible contamination risk that may arise from the vaginal and rectal ultrasound probe used to monitor the images of the patient's uterus and ovaries.

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

• Probe Cover Image

• Probe Cover Dimensions

	DIMENSIONS(CM)	
REF CODES	A	B
219.10.008.01 219.10.009.01 219.10.010.01 219.10.011.01 219.10.012.01 219.10.014.01	15	245
219.10.016.01 219.10.017.01 219.10.018.01 219.10.019.01 219.10.020.01 219.10.021.01	15	90
219.10.022.01	14	90
219.10.028.01	14	145
	9	90
	10	60

	15	60
	5	60
	35	3
	15	244
	13	240
	14	60
	13	245
	4	60

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

Available Materials:

PE transparent 35-40 microns

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 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	2696	CE marking
Single use (do not re-use)				