

## ULTRASOUND PROBE COVER KIT

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

|                                                                         |                                                                                                                                                                                                                                                            |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>Product Description</li></ul>     | <ul style="list-style-type: none"><li>Protective equipment used by doctors or nurses for surgical operations to prevent the possible risk of infection.</li></ul>                                                                                          |
| <ul style="list-style-type: none"><li>Product Class</li></ul>           | <ul style="list-style-type: none"><li>(EU) 2017/745 Medical Device Regulation – Class Business Rule I</li></ul>                                                                                                                                            |
| <ul style="list-style-type: none"><li>Manufacturer's Location</li></ul> | <ul style="list-style-type: none"><li>Tio Medikal 2/20 Sokak No:53 (Begos 3.Kuzey Giriş), 35400 Buca OSB / Buca / İzmir</li></ul>                                                                                                                          |
| <ul style="list-style-type: none"><li>Purpose of Usage</li></ul>        | <ul style="list-style-type: none"><li>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.</li></ul> |

### 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

### • Ultrasound Probe Cover Kit Image

### • Ultrasound Probe Cover Dimensions

| REF CODES                                                                                         | DIMENSIONS(CM) |     |
|---------------------------------------------------------------------------------------------------|----------------|-----|
|                                                                                                   | A              | B   |
| 219.10.008.01 219.10.009.01 219.10.010.01 219.10.011.01 219.10.012.01 219.10.014.01 219.10.016.01 | 15             | 245 |
| 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

• **Ultrasound Probe Cover Kit Content**

|   | Ultrasound Probe Cover Kit Content | Size                           | QTY |
|---|------------------------------------|--------------------------------|-----|
| • | Ultrasound Probe Cover             | Dimensions stated in the table | 1   |
| • | Rubber Bands/Straps                |                                | 2   |
| • | Steril Gel Pack                    | 20 ml                          | 1   |

**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)             |                    |                                                                  |      |                              |