

## PLAIN DRAPE

(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 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>These products are used as a protective barrier before, during and after surgical procedures to prevent the risk of infection between patients, doctors, nurses or medical professionals in hospitals, clinics or intensive care units.</li></ul> |

### 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 Devices Quality Management System
- 9001:2015 Quality Management System
- TS EN 13795 Surgical Clothing and Drapes
- 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

- Plain Drape Image

- Plain Drape Dimensions

|               | DIMENSIONS(CM) |     | NUMBER IN PACKAGE |          |          |
|---------------|----------------|-----|-------------------|----------|----------|
| REF CODES     | A              | B   |                   | 50X80X50 | 40X60X40 |
| 444.03.001.01 | 50             | 50  |                   | 1000     | 500      |
| 444.03.002.01 | 60             | 60  |                   | 1000     | 500      |
| 444.03.003.01 | 75             | 75  |                   | 750      | 300      |
| 444.03.004.01 | 100            | 100 |                   | 350      | 150      |
| 444.03.005.01 | 100            | 150 |                   | 250      | 100      |
| 444.03.006.01 | 100            | 120 |                   | 200      | 100      |

|               |     |     |     |    |
|---------------|-----|-----|-----|----|
| 444.03.007.01 | 150 | 180 | 125 | 50 |
| 444.03.008.01 | 150 | 200 | 125 | 50 |

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

**Available Materials:**

**01** - SMS (Spunbond PP/Meltblown/Spunbond PP) , 35-43 gr/m2

**02** - Dublex (PE /Viscose or PE/Spunbond PP) ,54- 56 gr/m2

|                                                      | EN 13795<br>requirements |                          |                               |                |                                                                                                                                                                                                                             |
|------------------------------------------------------|--------------------------|--------------------------|-------------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Characteristic                                       | Test Method              | High<br>performance      | Results                       | Main<br>fabric |                                                                                                                                                                                                                             |
|                                                      |                          | Critical product<br>area | Less critical<br>product area |                |                                                                                                                                                                                                                             |
| Resistance to microbial<br>penetration - Dry (CFU)   | EN ISO 22612             | Not required             | <300                          | Conformed      | <ul style="list-style-type: none"> <li>SS Hydrophobic Spunbond</li> <li>SS Hydrophylic Spunbond</li> <li>Surgical drape and gowns-Blue/white non woven</li> <li>Surgical drape and gowns-Blue laminated nonwoven</li> </ul> |
| Resistance to microbial<br>penetration - Wet ( / s)  | EN ISO 22610             | 6,0                      | Not required                  | Conformed      | <ul style="list-style-type: none"> <li>SS Hydrophobic Spunbond</li> <li>SS Hydrophylic Spunbond</li> <li>Surgical drape and gowns-Blue/white non woven</li> <li>Surgical drape and gowns-Blue laminated nonwoven</li> </ul> |
| Cleanliness - Microbial<br>(CFU/100cm <sup>2</sup> ) | EN ISO 11737-1           | <300                     | <300                          | Conformed      | <ul style="list-style-type: none"> <li>SS Hydrophobic Spunbond</li> <li>SS Hydrophylic Spunbond</li> <li>Surgical drape and gowns-Blue/white non woven</li> <li>Surgical drape and gowns-Blue laminated nonwoven</li> </ul> |
| Cleanliness - Particulate matter<br>(IPM)            | EN ISO 9073-10           | <3,5                     | <3,5                          | Conformed      | <ul style="list-style-type: none"> <li>SS Hydrophobic Spunbond</li> <li>SS Hydrophylic Spunbond</li> <li>Surgical drape and gowns-Blue/white non woven</li> <li>Surgical drape and gowns-Blue laminated nonwoven</li> </ul> |
| Linting (Log <sub>10</sub> (lint count))             | EN ISO 9073-10           | <4,0                     | <4,0                          | Conformed      | <ul style="list-style-type: none"> <li>SS Hydrophobic Spunbond</li> <li>SS Hydrophylic Spunbond</li> <li>Surgical drape and gowns-Blue/white non woven</li> <li>Surgical drape and gowns-Blue laminated nonwoven</li> </ul> |
| Resistance to liquid<br>penetration                  | EN 13795                 | $\geq 100$               | $\geq 10$                     | Conformed      | <ul style="list-style-type: none"> <li>SS Hydrophobic Spunbond</li> <li>SS Hydrophylic Spunbond</li> <li>Surgical drape and gowns-Blue/white non woven</li> <li>Surgical drape and gowns-Blue laminated nonwoven</li> </ul> |
| Bursting strength - dry                              | EN 13795                 | $\geq 40$                | $\geq 40$                     | Conformed      | <ul style="list-style-type: none"> <li>SS Hydrophobic Spunbond</li> <li>SS Hydrophylic Spunbond</li> <li>Surgical drape and gowns-Blue/white non woven</li> <li>Surgical drape and gowns-Blue laminated nonwoven</li> </ul> |

|                         |          |              |      |           |                                                                                                                                                                                                                             |
|-------------------------|----------|--------------|------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Bursting strength - wet | EN 13795 | Not required | ≥ 40 | Conformed | <ul style="list-style-type: none"> <li>SS Hydrophobic Spunbond</li> <li>SS Hydrophilic Spunbond</li> <li>Surgical drape and gowns-Blue/white non woven</li> <li>Surgical drape and gowns-Blue laminated nonwoven</li> </ul> |
| Tensile strength - dry  | EN 13795 | ≥ 20         | ≥ 20 | Conformed | <ul style="list-style-type: none"> <li>SS Hydrophobic Spunbond</li> <li>SS Hydrophilic Spunbond</li> <li>Surgical drape and gowns-Blue/white non woven</li> <li>Surgical drape and gowns-Blue laminated nonwoven</li> </ul> |
| Tensile strength - wet  | EN 13795 | Not required | ≥ 20 | Conformed | <ul style="list-style-type: none"> <li>SS Hydrophobic Spunbond</li> <li>SS Hydrophilic Spunbond</li> <li>Surgical drape and gowns-Blue/white non woven</li> <li>Surgical drape and gowns-Blue laminated nonwoven</li> </ul> |

## Biocompatibility

Biocompatibility studies has been done and test results are given in the below table. Test results are within limits.

| <i>Test Name</i>                       | <i>Test Method</i> | <i>Test facility</i> | <i>Report No</i> | <i>Report Date</i> | <i>Result</i>    |
|----------------------------------------|--------------------|----------------------|------------------|--------------------|------------------|
| <i>Cytotoxicity</i>                    | ISO10993-5:2010    | HACETTEPE UNIVERSITY | ARGEDS-2016/37   | 01.08.2016         | <i>Confirmed</i> |
| <i>Sensitizasyon Sensitization</i>     | ISO10993-10:2014   | HACETTEPE UNIVERSITY | ARGEDS-2016/37   | 24.10.2016         | <i>Confirmed</i> |
| <i>Cilt İrritasyon Skin Irritation</i> | ISO10993-10:2014   | HACETTEPE UNIVERSITY | ARGEDS-2016/37   | 11.06.2016         | <i>Confirmed</i> |

Biocompatibility Study Documentation

## 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 drapes, which helps the user to follow patient direction and unfolding directions.
- For the incision film or adhesive tape on the drapes, first of all peel the carrier and fix the drape on the operational area of the patient. After then unfold the drape by following the directions.
- Surgical drapes are ready for the operation, when they are completely unfolded.

|                                        |                    |                                                                  |      |                              |
|----------------------------------------|--------------------|------------------------------------------------------------------|------|------------------------------|
| 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)             |                    |                                                                  |      |                              |