



# TECHNICAL DATA SHEET

## FULL REINFORCED SURGICAL GOWN

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

### Full Reinforced Surgical Gown

|                                  |   |
|----------------------------------|---|
| ▶ <b>Product Description</b>     | ▶ Protective equipment used by doctors or nurses for surgical operations to prevent the possible risk of infection.   |
| ▶ <b>Product Class</b>           | ▶ (EU) 2017/745 Medical Device Regulation – Class Business Rule I   |
| ▶ <b>Manufacturer's Location</b> | ▶ Tio Medikal 2/20 st. No.53 (Begos 3. North Entrance, 35400 Buca OSB/Buca/İzmir  |
| ▶ <b>Purpose of usage</b>        | ▶ These products are used as a protective barrier before, during and after surgical operations to prevent the risk of infection between patients, doctors, nurses or medical professionals in hospitals, clinics or intensive care units. |

#### Quality

- Produced under ISO 13485:2016 and 13795-1 quality management standards.
- It has \*CE certificate.

#### Bio-Compatibility

- Does not contain latex.
- Sterilised with ethylene oxide.

#### Related Standart

- 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 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

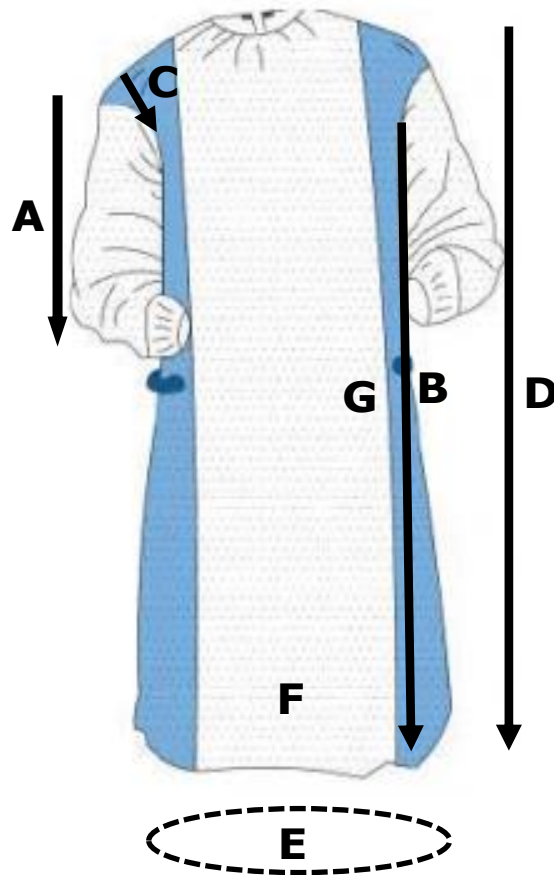
## Country of Origin

- This disposable Full Reinforced Surgical Gown is entirely  
manufactured in TURKEY



**Figure 1.** Full Reinforced Surgical

# 1. Full Reinforced Surgical Gown Sizes



**Figure 1.** Full Reinforced Apron Technical Demonstration

**Available Materials:** SMS (Spunbond PP/Meltblown/Spunbond PP) 35 gr/m<sup>2</sup> Reinforced fabric (PE+spunbond) 28gr

| REF . CODES              | DIMENSIONS (cm) |     |    |    |     |    |    | Pieces in Box |          |
|--------------------------|-----------------|-----|----|----|-----|----|----|---------------|----------|
|                          | A               | B   | C  | D  | E   | F  | G  | 50×80×50      | 40×60×40 |
| <b>L 333.03.F01.01</b>   | 145             | 117 | 29 | 60 | 150 | 50 | 70 | 80            | 40       |
| <b>XL 334.03.F01.01</b>  | 150             | 125 | 35 | 63 | 160 | 50 | 85 | 75            | 35       |
| <b>XXL 335.03.F01.01</b> | 155             | 125 | 35 | 63 | 160 | 50 | 85 | 65            | 25       |

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

|   |                | EN 13795 requirements |                            |           |  |
|---|----------------|-----------------------|----------------------------|-----------|--|
| Characteristic                                    | Test Method    | High performance      |                            | Results   | Main fabric  |
|   |                | Critical product area | Less critical product area |           |  |
| Resistance to microbial penetration - Dry (CFU)   | EN ISO 22612   | Not required          | <300                       | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Resistance to microbial penetration - Wet (1B)    | EN ISO 22610   | 6,0                   | Not required               | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Cleanliness - Microbial (CFU/100cm <sup>2</sup> ) | EN ISO 11737-1 | <300                  | <300                       | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Cleanliness - Particulate matter (PM)             | EN ISO 9073-10 | <3,5                  | <3,5                       | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Linting (Log <sub>10</sub> (lint count))          | EN ISO 9073-10 | <4,0                  | <4,0                       | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Resistance to liquid penetration                  | EN 13795       | ≥ 100                 | ≥ 10                       | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Bursting strength - dry                           | EN 13795       | ≥ 40                  | ≥ 40                       | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Bursting strength - wet                           | EN 13795       | Not required          | ≥ 40                       | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Tensile strength - dry                            | EN 13795       | ≥ 20                  | ≥ 20                       | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Tensile strength - wet                            | EN 13795       | Not required          | ≥ 20                       | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |

# BIOCOMPATIBILITY


















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

Table 31 Biocompatibility Study Documentation

| <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>Sensitization</i>   | ISO10993-10:2014   | HACETTEPE UNIVERSITY | ARGEDS-2016/37   | 24.10.2016         | <i>Confirmed</i> |
| <i>Skin Irritation</i> | ISO10993-10:2014   | HACETTEPE UNIVERSITY | ARGEDS-2016/37   | 11.06.2016         | <i>Confirmed</i> |

## Instruction for use:

1. The package of product shall be opened in sterile and aseptic conditions.
2. For a clean peel, open the package from the direction of the arrow slowly .
3. In order to wear the surgical gown, first of all put your hands into armholes.
4. Keep the gown away from your body and let it to be unfolded completely.
5. Slip your arms into sleeves.
6. The helping nurse will pull the gown over shoulders with touching only inside of the gown.
7. Make sure to overlap velcro bands on the neck part and arrange the distance.
8. Tie the inner belts of the gown.
9. Wear the gloves.
10. Hold the belt card and after pulling the outer belts from the card by the help of nurse, tie it together with the other outer belt on the left hand side.

|   |  |   |                    |   |  |   |                        |
|---|--|---|--------------------|---|--|---|------------------------|
|  | 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 barrier system |  | CE Marking             |
|  | Keep Dry                               |  | Batch Code         |  | Caution  |  | Medical device         |
|  | Unique device identifier               |   |                    |   |  |   |                        |