# TECHNICAL DATA SHEET
# GOWN FOR PATIENT - LONG SLEEVE

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

## GOWN FOR PATIENT - LONG SLEEVE

| | |
|---|---|
| **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 st. No.:53 (Begos 3. North Entrance, 35400 Buca OSB/Buca/İzmir |
| **Purpose of usage** | These products are used as a protective barrier before, duringand 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.

### Related Standart
- ISO 13485:2016 Medical Devices Quality Management System
- 9001:2015 Quality Management System
- TS EN 13795 Surgical Clothing and Drapes

### Shelf Life
- 5 years

## Country of Origin

- This disposable Patient Gown is completely made in Turkey

**Figure 1.** GOWN FOR PATIENT - LONG SLEEVE

# 1. GOWN FOR PATIENT - LONG SLEEVE

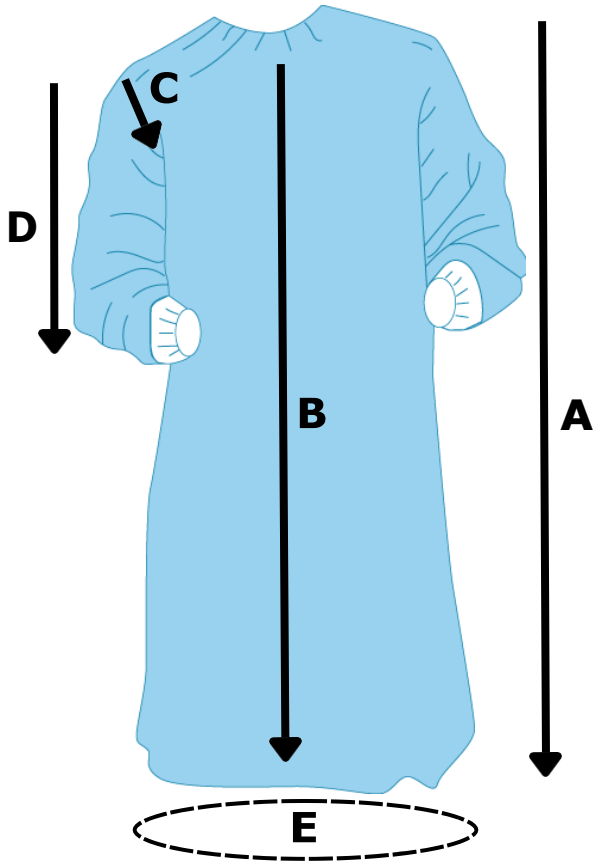


**Figure 1.** GOWN FOR PATIENT - LONG SLEEVE

**Available Materials:** SMS (Spunbond PP/Meltblown/Spunbond PP) 35 gr/m2

| | | DIMENSIONS (cm) | | | | | Pieces in Box | |
|---|---|---|---|---|---|---|---|---|
| | REF . CODES | A | B | C | D | E | 50×80×50 | 40×60×40 |
| M | 352.06.P01.02 | 115 | 105 | 29 | 58 | 140 | 100 | 50 |
| L | 353.06.P01.02 | 125 | 115 | 29 | 60 | 145 | 90 | 40 |
| XL | 354.06.P01.02 | 130 | 120 | 32 | 62 | 150 | 80 | 35 |
| XXL | 355.06.P01.02 | 135 | 125 | 32 | 64 | 160 | | |

**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 (IB) | 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/100cm²) | 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 (IPM) | 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 (Log10 (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

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

Table 31 Biocomtability Study Documentation

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

## Instruction for use:

1. The package of product shall be opened in sterile and aceptic conditions.
2. For a clean peel, open the package from the direction of the arrow slowly .
3. There are labels or marks on the drapes, which helps the user to follow the patient direction and unfolding directions.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Do not use if package is damaged | | Manufacturer | | Single Use (Do not re-use) | | Use by date |
| | Do not expose the product to sunlight. | REF | Catalogue number | | Consult instructions for use | 30 °C 10 °C | Temperature Limitation |
| | Do not re-sterilize | | Manufacturing Date | STERILE EO | Sterilized using Ethyleneoxide and Single sterile barier system | CE 2696 | CE Marking |
| | Keep Dry | LOT | Batch Code | | Caution | MD | Medical device |
| UDI | Unique device identifier | | | | | | |