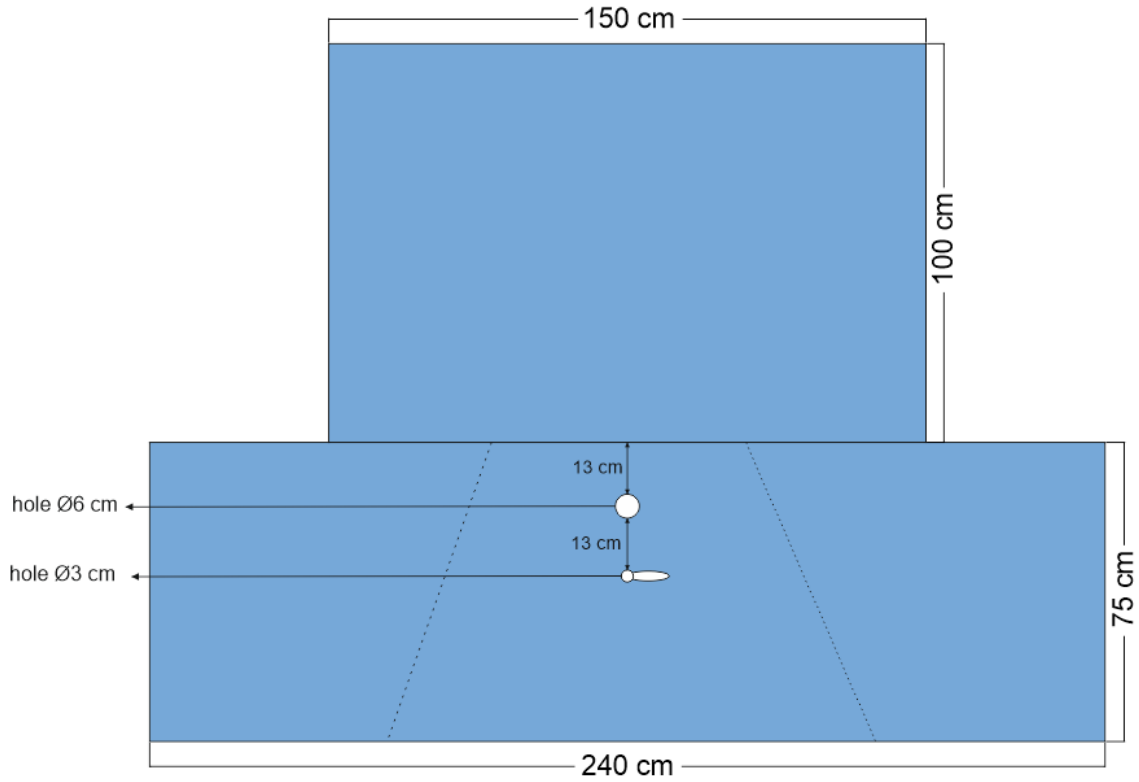


UROLOGY DRAPE PACK
REF.NO:170.001.01
STANDARD PRODUCT DATA SHEET
KY-PD-038

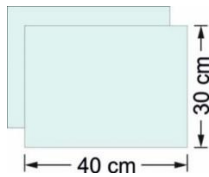


STANDARD PRODUCT DATA SHEET
UROLOGY DRAPE PACK
170.001.01

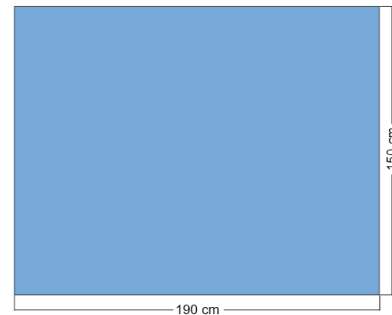
1) PRODUCT COMPONENTS



ITEM 1
Urology Drape
175x240 cm



ITEM 2
Hand Towel
30x40 cm



ITEM 3
Back Table Cover
150x190
(All of the product components are wrapped into back table cover)

**STANDARD PRODUCT DATA SHEET
UROLOGY DRAPE PACK
170.001.01**

2) DETAILS OF PRODUCT COMPONENTS

| ITEM | QTY | PRODUCT | FABRIC TYPE | DIMENSION | COLOUR |
|------|-----|------------------|-----------------------|------------|--------|
| 1 | 1 | Urology Drape | Biflex 56gr/m2 (+/-3) | 175x240 cm | Blue |
| 2 | 2 | Hand Towel | Cellulose | 30x40 cm | White |
| 3 | 1 | Back Table Cover | Biflex 56gr/m2 (+/-3) | 150x190 cm | Blue |

3) GENERAL INFORMATION

| Product Description | UROLOGY DRAPE PACK |
|------------------------|---|
| Reference Code | 170.001.01 |
| Packing Quantity | 1 pc |
| Quantity Per Box | 15 pcs |
| Sterilization | EO (Ethylene Oxide) |
| Certificates | EC Certificate |
| | ISO 13485:2016 |
| Standards | EN ISO 14971:2019 |
| | EN 13795-1:2019 |
| | EN ISO 11135:2014 |
| | EN 556-1:2001 |
| | EN ISO 15223-1:2016 |
| | EN ISO 11737-1:2018 |
| | EN ISO 11737-2:2020 |
| | EN ISO 14644-1:2015 |
| | EN ISO 14644-2:2015 |
| | EN 17141:2020 |
| | EN ISO 10993-1:2020 |
| | EN ISO 10993-5:2009 |
| | EN ISO 10993-7:2008 |
| | EN ISO 10993-10:2010 |
| | EN ISO 20417:2021 |
| | EN ISO 11607-1:2020 |
| | EN ISO 11607-2:2020 |
| | EN 62366-1:2015 |
| Instructions For Usage | This set can be used during the surgery operations. This product is disposable and it prevents the bacterial transfer between the medical team and the patient, reduces the occurring of possible contamination and infection between the patient and the medical team. |
| Expiry Date | 3 years |

**STANDARD PRODUCT DATA SHEET
UROLOGY DRAPE PACK
170.001.01**

5) PACKAGING

| | | |
|--|--|---------------|
| All production | Clean Room Conditions, Medical Folding, Sterilization Bag, Peelable label, | |
| Labelling of product | Each unit <ul style="list-style-type: none"> - Article number, - Lot number, - Manufacturer , - Production date, - Expiry date, - EO Sterilization, - Single use, - CE, - Other customer requests, | |
| Packaging | <u>Pallet system</u> | <u>Carton</u> |
| | Height (cm) -A | 40 |
| | Width (cm) - B | 60 |
| | Length (cm) - C | 40 |
|  | | |
| Storage Instructios | <p>HANDLING AND STORAGE: Products are sterile and must be stored in its original closed carton box, in a dry place. The products must be used as soon as the package is opened in the operation room. Do not expose to humidity and direct heat or sunlight.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>45°C</p>  <p>Upper limit of temperature</p> </div> <div style="text-align: center;"> <p>% 70</p>  <p>Humidity Limitation</p> </div> </div> | |