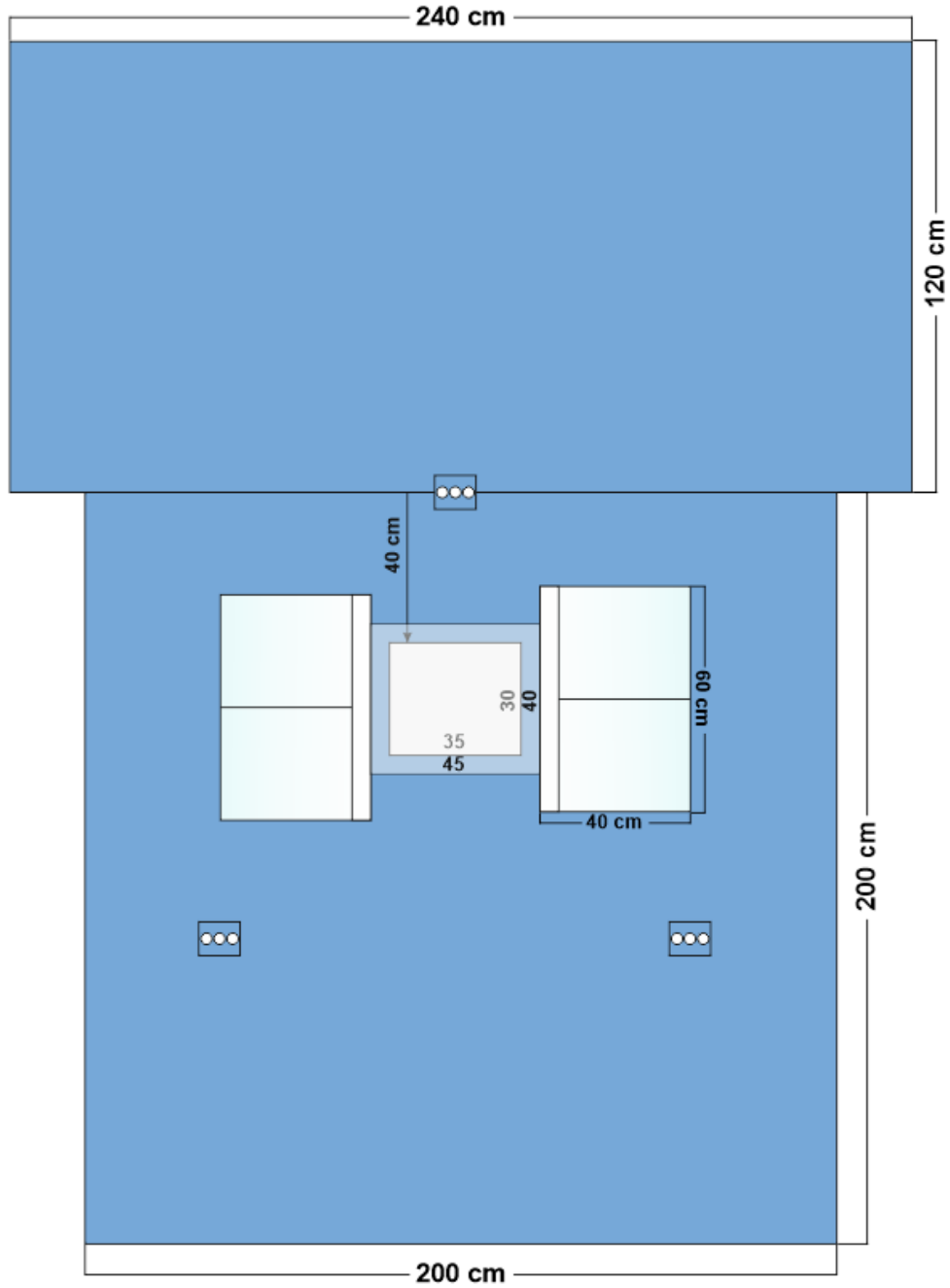


LAPAROTOMY DRAPE
REF.NO:215.001.01
STANDARD PRODUCT DATA SHEET
KY-PD-008



STANDARD PRODUCT DATA SHEET
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215.001.01

1) PRODUCT COMPONENTS



ITEM 1

Laparotomy Drape
240x320 cm

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2) DETAILS OF PRODUCT COMPONENTS

| ITEM | QTY | PRODUCT | FABRIC TYPE | DIMENSION | COLOUR |
|------|-----|-------------------------|-----------------------|------------|-------------|
| 1 | 1 | Laparotomy Drape | Biflex 56gr/m2 (+/-3) | 240x320 cm | Blue |
| | 2 | Liquid Collection Pouch | PE 45 Micron (+/-5) | 40x60 cm | Transparent |

3) GENERAL INFORMATION

| | |
|-------------------------------|---|
| Product Description | LAPAROTOMY DRAPE |
| Reference Code | 215.001.01 |
| 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 product 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 |

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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> | |