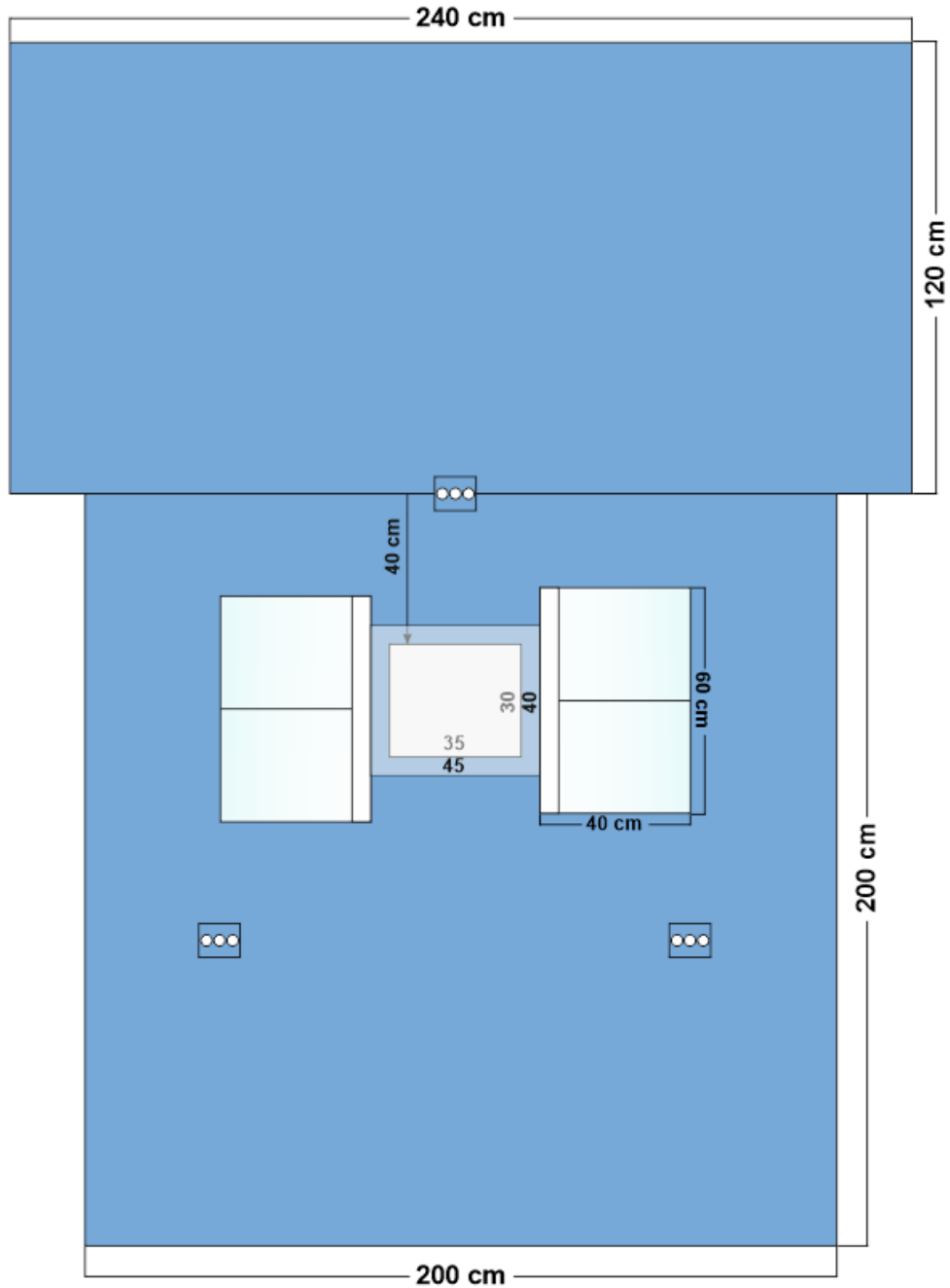


LAPAROTOMY DRAPE PACK
REF.NO:115.001.01
STANDARD PRODUCT DATA SHEET
KY-PD-005



STANDARD PRODUCT DATA SHEET
LAPAROTOMY DRAPE PACK
115.001.01

1) PRODUCT COMPONENTS



ITEM 1

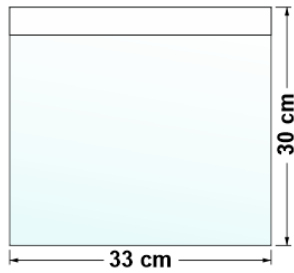
Laparotomy Drape
240x320 cm



STANDARD PRODUCT DATA SHEET

LAPAROTOMY DRAPE PACK

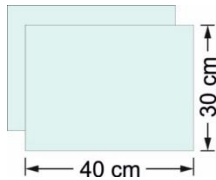
115.001.01



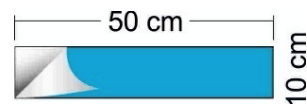
ITEM 2
Diathermy Bag
30x33 cm



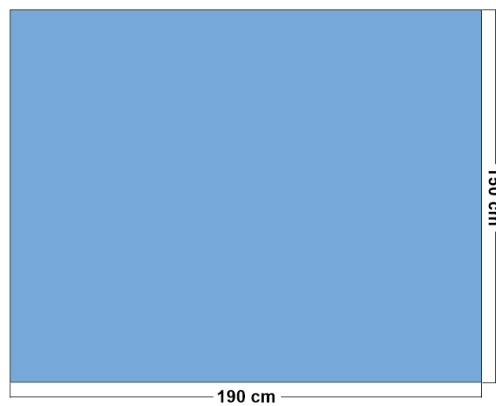
ITEM 3
Mayo Stand Cover
78x145 cm (unfolded)



ITEM 4
Hand Towels
30x40 cm



ITEM 5
OP-Tape
10x50 cm



ITEM 6
Back Table Cover
150x190 cm

(All of the product components are wrapped into back table cover)

STANDARD PRODUCT DATA SHEET
LAPAROTOMY DRAPE PACK
115.001.01

2) DETAILS OF PRODUCT COMPONENTS

ITEM	QTY	PRODUCT	FABRIC TYPE	DIMENSION	COLOUR
1	1	Laparotomy Drape	Biflex 56gr/m ² (+/-3)	240x320 cm	Blue
	2	Liquid Collection Pouch	PE 45 Micron (+/-5)	40x60 cm	Transparent
2	1	Diathermy Bag	PE 45 Micron (+/-5)	30x33 cm	Transparent
3	1	Mayo Stand Cover	Pe+nonwoven	78x145 cm	Blue
4	4	Hand Towels	Cellulose	30x40 cm	White
5	2	OP-Tape	Sms+hotmelt+silicon paper	10x50 cm	Blue
6	1	Back Table Cover <i>(All of the product components are wrapped into back table cover)</i>	Biflex 56gr/m ² (+/-3)	150x190 cm	Blue

STANDARD PRODUCT DATA SHEET

LAPAROTOMY DRAPE PACK

115.001.01

3)GENERAL INFORMATION

Product Description	LAPAROTOMY DRAPE PACK
Reference Code	115.001.01
Packing Quantity	1 pc
Quantity Per Box	10 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
LAPAROTOMY DRAPE PACK
 115.001.01

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>	