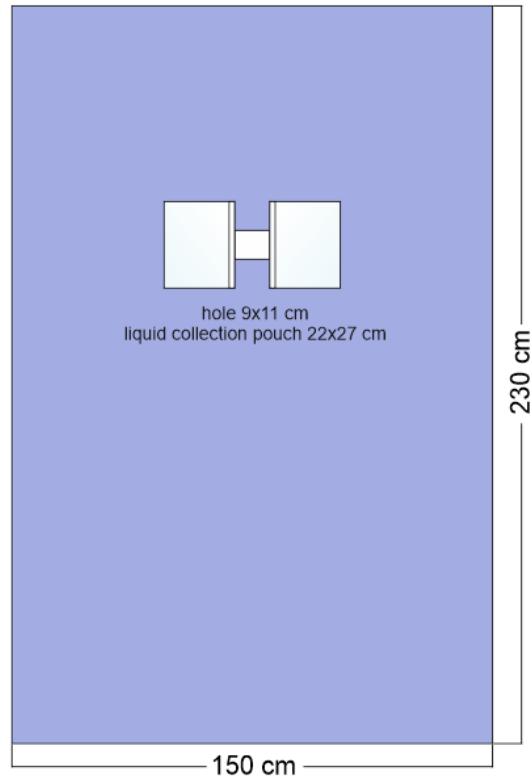


OPHTHALMIC DRAPE PACK
REF.NO:182.001.01
STANDARD PRODUCT DATA SHEET
KY-PD-046



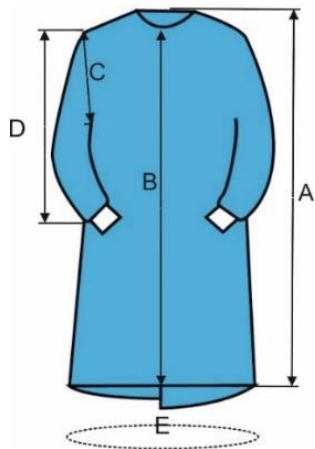
STANDARD PRODUCT DATA SHEET
OPHTHALMIC DRAPE PACK
182.001.01

1) PRODUCT COMPONENTS



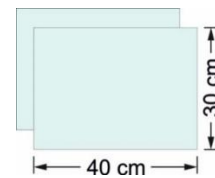
ITEM 1

Opthalmic Drape w/single pouch
150x230 cm



ITEM 2

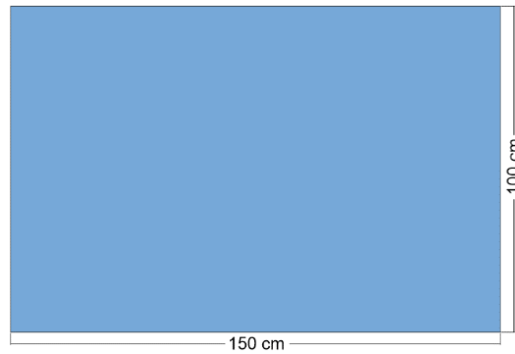
Standard Surgical Gown
L



ITEM 3

Hand Towel
30x40 cm

**STANDARD PRODUCT DATA SHEET
OPHTALMIC DRAPE PACK
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ITEM 4

Back Table Cover
100x150 cm

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

2) DETAILS OF PRODUCT COMPONENTS

ITEM	QTY	PRODUCT	FABRIC TYPE	DIMENSION	COLOUR
1	1	Ophtlamic Drape	Sms 43gr/m2 (+/-3)	150x230 cm	Blue
2	2	Standard Surgical Gown	Sms 43gr/m2 (+/-3)	L	Blue
5	2	Hand Towel	Cellulose	30x40 cm	White
6	1	Back Table Cover	Biflex 56gr/m2 (+/-3)	100x150 cm	Blue

STANDARD SURGICAL GOWN MEASUREMENT (cm)

<u>SIZE</u>	<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>	<u>E</u>
L	127	117	29	60	150

**STANDARD PRODUCT DATA SHEET
OPHTHALMIC DRAPE PACK
182.001.01**

3)GENERAL INFORMATION

Product Description	OPHTHALMIC DRAPE PACK
Reference Code	182.001.01
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
OPHTHALMIC DRAPE PACK
182.001.01

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>	