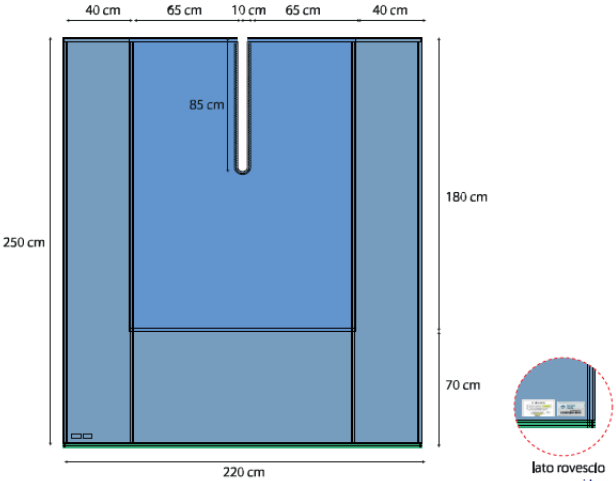
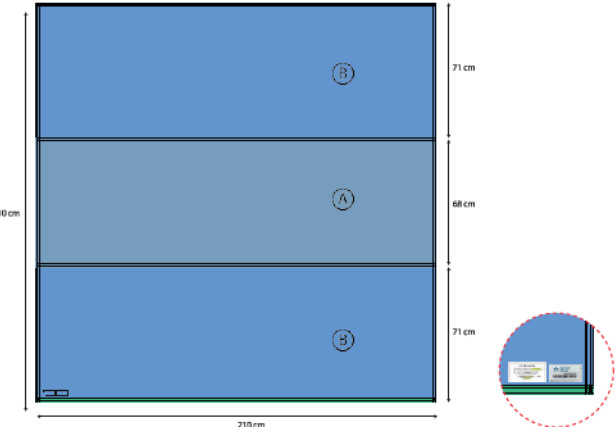
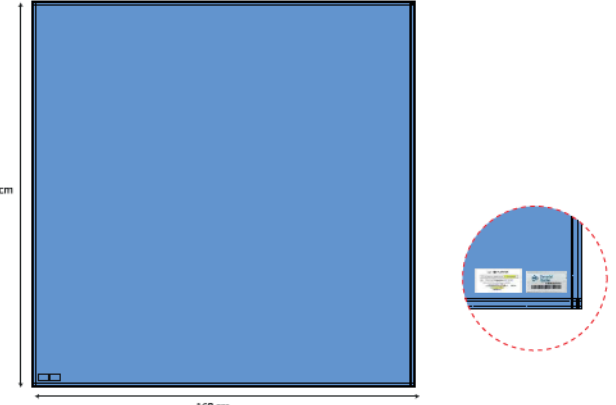
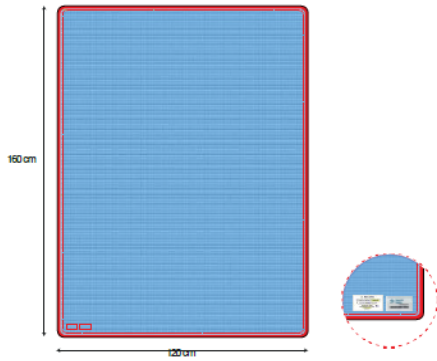




ASSOSISTEMA

Textilia draperingsmaterial -flergångs

ITEM PICTURE	COLOR	ITEM CODE	FABRIC/ NORM
ORTO -SET			
	Light Blue	220X250 ORTHO SLIT DRAPE	Medical Microfibre 99%polyester/ 1%carbon + 3L laminate PU EN 13795 Quality Mgmt EN 13485
	Light Blue	210X210 TABLE DRAPE SHEET	Medical Microfibre 99%polyester/ 1%carbon + 3L laminate PU EN 13795 Quality Mgmt EN 13485
	Light Blue	160X160 MULTI-USE DRAPE	Medical Microfibre 99%poly/ 1%carbon EN 13795 Quality Mgmt EN 13485



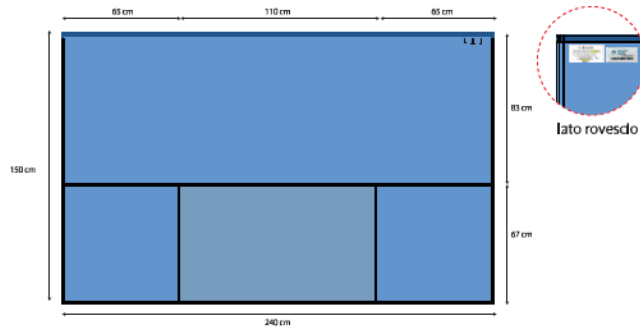
Light
Blue

120X160
ABSORBENT
DRAPE

100%
texturized
polyester

Quality Mgmt
EN 13485

UNIVERSAL -SET

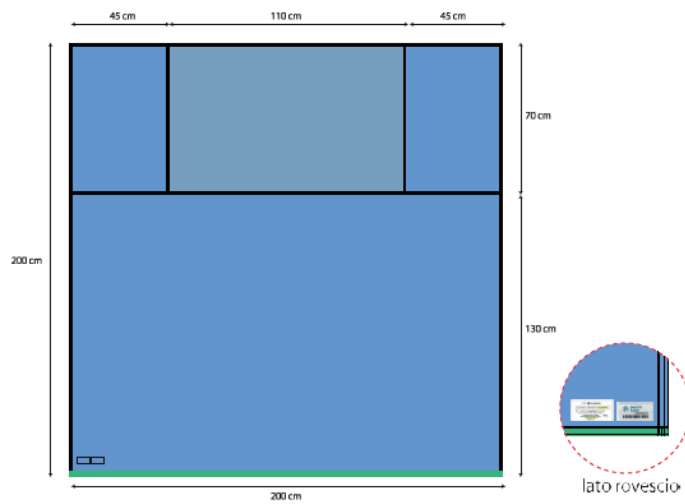


Light Blue

150 x 240
GENERAL
TOP-HEAD
DRAPE

Medical
Microfibre
99%polyester/
1%carbon
+
3L laminate
PU
EN 13795

Quality Mgmt
EN 13485

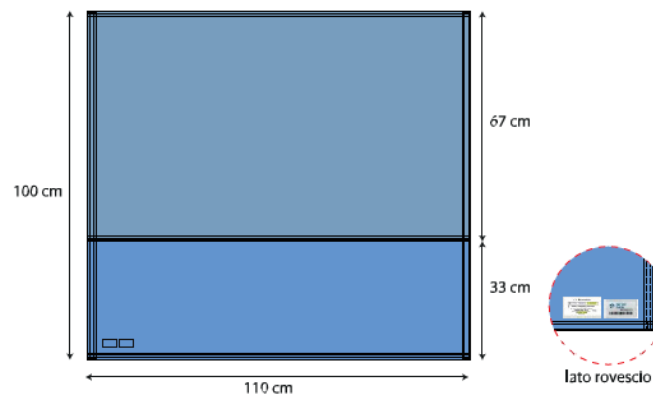


Light Blue

200 x 200
FOOT DRAPE

Medical
Microfibre
99%polyester/
1%carbon
+
3L laminate
PU
EN 13795

Quality Mgmt
EN 13485



Light Blue

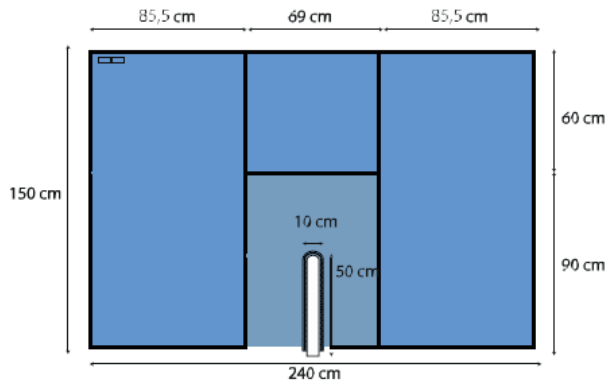
2X
100 x 110
SIDE DRAPE

Medical
Microfibre
99%polyester/
1%carbon
+
3L laminate
PU
EN 13795

Quality Mgmt
EN 13485

	<p>Light Blue</p>	<p>140 x 80 MAYO DRAPE</p>	<p>Medical Microfibre 99%polyester/ 1%carbon + 3L laminate PU EN 13795 Quality Mgmt EN 13485</p>
	<p>Light Blue</p>	<p>160 X 120 ABSORBENT DRAPE</p>	<p>100% texturized polyester Quality Mgmt EN 13485</p>

NEURO / ÖNH -SET



Light Blue

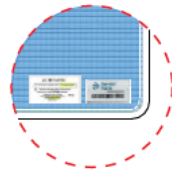
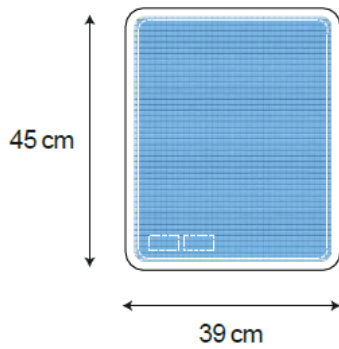
150 X 240
HEAD SLIT
DRAPE

Medical
Microfibre
99%polyester/
1%carbon

+
3L laminate
PU

EN 13795

Quality Mgmt
EN 13485

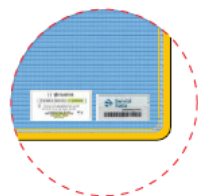
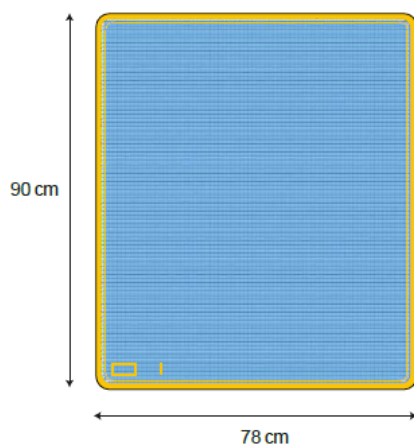


Light
Blue

45 X 39
ABSORBENT
DRAPE

100%
texturized
polyester

Quality
Mgmt EN
13485



Light
Blue

90 X 78
ABSORBENT
DRAPE

100%
texturized
polyester

Quality
Mgmt EN
13485

General info:

- *drape made of Medical Microfiber (biocompatible, latex free, barrier to virus and bacterial passage)*
- *lint free*
- *Absorbing 3L laminate surface*
- *seams in water-repellent polyester thread*

Intended use: Medical Device for setting up the operating theatre. Reprocessable. Steam and ETO sterilizable

EC TRACEABILITY LOT LABEL

EMDN CODE REFERENCE: T020199 – HIGH AND STANDARD PERFORMANCE SURGERY DRAPES FOR OPERATING ROOM
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 RELATING TO MEDICAL DEVICES, AMENDING DIRECTIVE 2001/83 / EC, REGULATION (EC) NO. 178/2002 AND REGULATION (EC) NO. 1223/2009 AND REPEALING COUNCIL DIRECTIVES 90/385 / EEC AND 93/42 / EEC. THE DEVICE HAS BEEN DESIGNED AND MANUFACTURED IN COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS PRESCRIBED IN ANNEX I OF DIRECTIVE 93 / 412 / EEC AND SUBSEQUENT AMENDMENTS AND ADDITIONS. DM RISK CLASS 1, ANNEX VIII. PROCEDURE CHOSEN FOR THE CONFORMITY ASSESSMENT: CLASS I, ANNEX IV (EC DECLARATION OF CONFORMITY). THE DEVICE IS RETAILED IN NON-STERILE PACKAGING. THE MANUFACTURER ALSO DECLARES TO HAVE ESTABLISHED AND TO MAINTAIN AN APPROPRIATE PROCEDURE TO ENSURE THE POST-SALES SURVEILLANCE REQUIRED BY DIRECTIVE 93/42 / EC AND SUBSEQUENT AMENDMENTS AND ADDITIONS. HARMONIZED STANDARDS REF.: ISO UNI EN 13485: 2016 - CE / EN 13795

Light Blue fabrics, Productions and manufacturing are Customized on order, a wide range of flatware cover drapes are available, suitable for universal and specific draping systems.

Reprocessable (up to 80x and above), Launderable and Sterilizable (by steam and ETO)

Gentle on the Environment, once they have reached end-of-life they can be downgraded for continuance as an alternate use product.

Reusable garments represent a simple transition towards Greening the Operating Room.

These products can easily and effectively be converted from high-cost, waste-generating single-use, to cost-effective, environmentally preferred, REUSABLES

TECHNICAL DATA SHEET DRAPE PU 3L LAMINATE

Product designation	Surgical Barrier fabric - ECO PU MEDICAL Surgery DRAPES
Color	Light blue
Construction	3 layer laminate
Face fabric:	100% PES warp knitted fabric Color light blue
Membrane:	Medical PU membrane
Back fabric:	100% PES warp knitted fabric Color light blue

<u>Properties according to EN 13795</u>	13795 Norm	Value ⁽¹⁾ NEW CONDITION	Value ⁽²⁾ AFTER 80 WDA	Unit
Resistance to germ penetration – dry	EN 22612	0	0	Log10 KBE
Resistance to germ penetration – wet	EN 22610	6,0	6,0	BI
Cleanliness – microbiological	EN ISO 1174-2	---- (3)	---- (3)	Log10 KBE/dm ²
Cleanliness – particulate matter	ISO CD9073-10	≤ 3 ⁽⁴⁾ (5)	≤ 3 ⁽⁴⁾ (5)	IPM
Linting	ISO CD9073-10	≤ 3,25	≤ 3,25	Log10 Partikel (3-25µm)
Resistance to liquid penetration	EN 20811	≥ 100	≥ 100	mbar
Burst pressure → dry → wet	EN ISO 13938-1	≥400 ≥400	≥350 ≥350	kPa
Tensile strength → dry warp → dry weft → wet warp → wet weft	DIN EN 29073-3	≥500 ≥450 ≥450 ≥400	≥400 ≥350 ≥350 ≥300	N

- (1) Values represent product quality in new condition
- (2) Values represent product quality at the end of life (80 cycles)
- (3) MicroBiological cleanliness is depending on the process of the reprocessor
- (4) Based on in house labRKI-lab process /external RKI-process at validated lab
- (5) Depending on reprocessor process

<u>Technical properties</u>	Norm	Value ⁽¹⁾ NEW CONDITION	Unit
Weight/per area	ISO 3801	175+/-10%	g/m ²
Burning Behaviour	DIN 66083	S-e	class
Liquid management	On the basis of ISO 9073-6	>99 ⁽²⁾	%
Skin compatibility	ISO 10993	No allergical	REACTIONS
Water vapor resistance	EN 11092	≤8	m ² Pa/W
Thermal resistance	EN 11092	>5	10 ⁻³ m ² K/W
Surface resistance warp weft	DIN 54345-5	10 ¹³ 10 ¹³	Ohm
Surface resistance Face fabric Back fabric	DIN 54345-1	4,4x10 ¹¹ 4,4x10 ¹¹	Ohm
Color fastness to abrasion → dry → wet	ISO 105-X12	4 4	Grade
Color fastness to washing	ISO 105-C06	4	Grade
Color fastness to perspiration → acidic → alkaline	ISO 105-E04	4 4	Grade
Color fastness to water	ISO 105-E01	4	Grade
Bacteriophages penetration	ASTM F 1671-97/ ISO 16004	No penetration	⁽¹⁾ ⁽²⁾
Virus penetration	ASTM F 1671-97/ ISO 16004	No penetration	⁽¹⁾ ⁽²⁾

(1) Values represent product quality in new condition

(2) Values represent product quality at the end of life (80 cycles)

TECHNICAL DATA SHEET MICROFIBER

Product designation	MEDICAL Microfiber
Color:	light blue
Application:	High and Standard Performance OR Drapes for Critical / less critical area
Constrution:	
→ Material:	99% polyester filaments 1% carbon fiber
→ Weave:	plain weave
→ Weight:	130 g/m ²
→ Width total:	160 cm
→ Finishing:	fluor carbon finishing (PFOA free)
→ Sterilizability :	steam sterilisable / ETO-sterilisable

Basic properties according to EN 13795	Standard	Value ¹⁾ Siomed	Value ²⁾ 13795 SP drapes Critical area	Value ³⁾ 13795 SP gowns Critical area	Value ⁴⁾ 13795 SP gowns- /drapes Less critical area	Unit
Resistance to liquid penetration	EN 20811	> 50	> 30	> 20	> 10	cm H ₂ O
Resistance to microbial penetration → wet	EN 22610	4,14	≥ 2,8	≥ 2,8	Not required	BI
Resistance to microbial penetration → dry	EN 22612	0	Not required	Not required	≤ 2	Log ₁₀ KBE
Cleanliness – particulate matter (foreign particle) → Outside → Inside	ISO/CD9073-10	1,9 ⁵⁾ 1,4 ⁵⁾	≤ 3,5	≤ 3,5	≤ 3,5	IPM
Linting → Outside → Inside	ISO/CD9073-10	2,0 1,8	≤ 4,0	≤ 4,0	≤ 4,0	Log ₁₀ particle (3-25 μm)
Bursting strength → dry → wet	EN ISO 13938-2	460 448	≥ 40 ≥ 40	≥ 40 ≥ 40	≥ 40 -	kPa kPa
Tensile strength → dry warp → dry weft → wet warp → wet weft	DIN EN 13934-1	693 583 678 595	≥ 15 ≥ 15 ≥ 15 ≥ 15	≥ 20 ≥ 20 ≥ 20 ≥ 20	≥ 20/15 ≥ 20/15 - -	N N N N

- 1) Values represent product quality after 15 reprocessing cycles (Wash, dry, autoclave) based on laboratory process., test results available up to 70 washing processes .
- 2) Values represent limit values according to 13795-3 Standard Performance OR-drapes, critical area
- 3) Values represent limit values according to 13795-3 Standard Performance OR-gowns, critical area
- 4) Values represent limit values according to 13795-3 Standard Performance OR-gowns and OR-drapes, less critical area
- 5) Depends on validated process of the individual laundry



ASSOSISTEMA

OEKO-TEX®
CONFIDENCE IN TEXTILES
STANDARD 100

Other properties	Standard	Value ¹⁾	Unit
Surface resistance	DIN 54345 - 1	Max. 10 ¹¹	Ohm
Comfort / Breathability	According to Hohenstein model	max. 3,5 = comfort "Very good"	Ret (m ² Pa/W)
Cytotoxicity	ISO 10993-52	No cytotoxic effects ²⁾	
Spray test	ISO 4920, 1992 / AATCC 22, 1989	5	Note
Washing shrinkage	WDA according to RKI-directive	< 5	%
Colorfastness to abrasion → dry → wet	ISO 105-X12	4- 5 4	grade grade
Colorfastness to washing	ISO 105-C06	4-5	grade
Colorfastness to water	ISO 105-E01	4-5	grade

1) Values represent product quality in new condition

2) Cytotoxicity test according to DIN EN ISO 10993-5

*****Test Method Breathability Test Ist. Hohenstein:**

Type SWEATING HOT PLATE /Sweating Hot Plate

Also known as **ISO - 11092 or Ret or Hohenstein test.**

In this test, tissue is placed over a porous (sintered) metal plate. The plate is heated and water is piped into the metal plate, simulating perspiration. The plate is then kept at a constant temperature. When water vapor passes through the plate and fabric, it causes an evaporative heat loss and therefore more energy is required to maintain the plate at a constant temperature. Ret is a measure of resistance to evaporative heat loss. The lower the Ret value, the lower the resistance to moisture transfer and thus the greater breathability.

Hohenstein added a unique aspect to their tests. They had real people wearing clothes made of fabrics of different Ret values and exercising on a treadmill. They collected the testers' comments and correlated them with the Ret values of the fabrics and came up with a Comfort Rating System.

Performance range:

Ret 0-6 Very good or extremely breathable. Comfortable at a higher activity rate.

Ret 6-13 Good or very breathable. Comfortable at a moderate activity rate.

Ret 13-20 Satisfactory or Breathable. Uncomfortable at high activity rate.

Ret 20-30 Unsatisfactory or slightly breathable. Moderate comfort at low activity rate.

Ret 30+ Unsatisfactory or non-breathable. Uncomfortable and short tolerance time.

Breathability/Breathability 3.5 = Very Good range

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