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Broche[®]
medical

PRODUCT CATALOGUE

Broche[®]
Medical

BRUCHE

nonwovens



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ABOUT US

Nurteks Tekstil ve Medikal San. Dış Tic. A.Ş. has started production and sale of disposable surgical gowns and surgical drape sets with **Broche**® brand in its own facilities in the beginning of 2006 to convey its experiment, in non-woven sector since 1995, to medical sector.

Nurteks Tekstil, having a well earned place in all over Turkey with **Broche**® brand by quick delivering all kinds of consumable goods, mostly gloves, which have been produced and, as well, imported since its establishment, 2006, has hold a prominent place and been an important brand, especially, in the markets of Europe, Africa and Middle East with its export activities.

Nurteks Tekstil, making use of ever developing technologies since the beginning of 2012, improved its all machine lines and sterilization devices, and extended its production and stock areas to a total 7.000 SM closed area.

Nurteks Tekstil is steadily carrying on its activities to hold the prominence to be one of the leading brands in the medical sector with high quality and fair price it has been offering in the market with **Broche**® brand.

Quality Policy;

- To make production in the medical sector with the latest technology and provide persistence in production quality and a quality management system.
- To enhance the customer satisfaction by taking any suggestions and complaints into consideration.
- To offer products and services in compliance with current laws and regulations by giving due importance to human health.

Certificates;

CE2195, ISO 13485, ISO 9001,

All drapes and gowns are

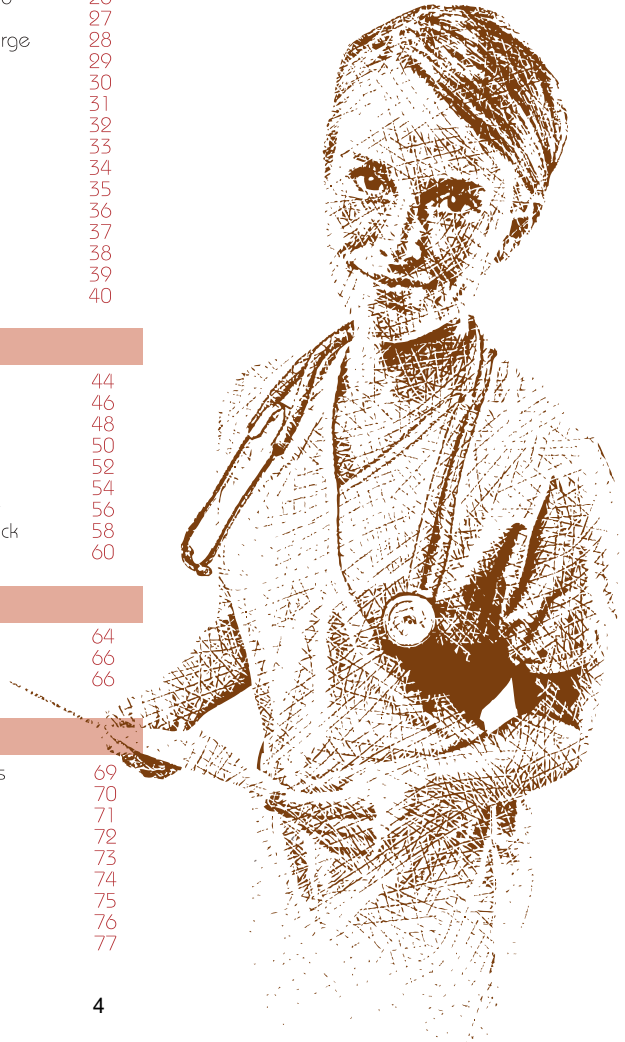
TS EN 13795 + A1 certified by TURKISH STANDARDS INSTITUTE.



EN 13795 + A1



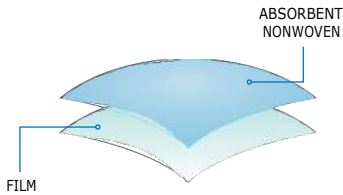
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NONWOVEN FABRICS

Two-Layered Drape Materials

Perfect for many applications, they are the result of the combination of a low-linting nonwoven or tissue paper with high absorbing properties with an impervious film acting as a liquid barrier.

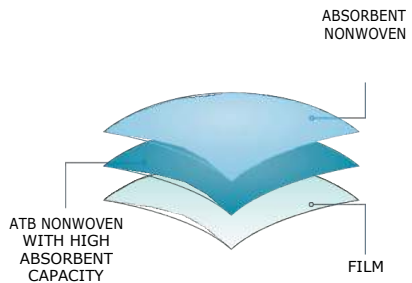
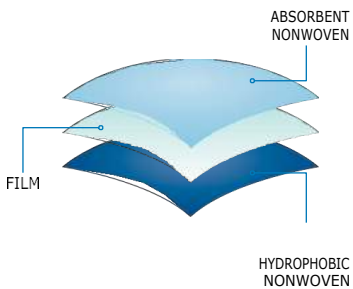


Absorbent Reinforcement Material for Critical Zones

BROCHE has developed a three-layered material specifically designed to enhance the absorption of liquids in critical zones.

Three-Layered Drape Materials

Capable of trapping liquid quickly and effectively, they are designed to be placed in direct contact with the skin of the patient and can be used for multiple purposes such as surgical drapes and kits.



Product list

PRODUCT CODE	APPLICATION	TOTAL BASIS WEIGHT (gsm)	COMPOSITION	
			RAW MATERIAL	BASIS WEIGHT (gsm)
TDL	Two-Layered Surgical Drape	54	Hydrophilic Viscose Nonwoven	25
			Rubber Based Hot Melt Adhesive	2
			Micro-embossed Cast PE Film	27
TDL3	Three-Layered Surgical Drape	70	Hydrophilic Viscose Nonwoven	28
			Rubber Based Hot Melt Adhesive	2
			Micro-embossed Cast PE Film	25
			White Hydrophobic SB Nonwoven	15
SE	Absorbent Reinforcement Material for Surgical Drape	80	Hydrophilic Viscose Nonwoven	28
			Rubber Based Hot Melt Adhesive	2
			High-AbsorbencyViscose Nonwoven	50
SE3	Absorbent Reinforcement Material for Surgical Drape (with PE Film)	105	Hydrophilic Viscose Nonwoven	28
			Rubber Based Hot Melt Adhesive	2
			High-AbsorbencyViscose Nonwoven	50
			Micro-embossed Cast PE Film	25
DL	Raw Viscose	28	Viscose (Standard production) • Ranges from 20 gsm to 50 gsm	28
PE	PE Film	25	PE Film (Standard production) • Ranges from 20 gsm to 100 gsm	25
TABLE CLOTH	TABLE COVER	60	Micro-embossed Cast PE Film	45
			High-AbsorbencyViscose Nonwoven	28

- Our products can be customized according to customer demands



EN 13795

European Standard for Surgical Drapes and Gowns

Introduction

This document provides an overview of the EN 13795 European Standard for surgical gowns and drapes, which outlines their performance requirements, test methodologies and explains the overall relevance to patients and the clinical staff.

The broad aim of EN 13795 is to establish an European recognised standard of quality and conformance to manufacturing, testing and performance specifications for all single-use and multiple-use surgical drapes and gowns.

Key aspects of Section 6



General requirements for Manufacturers, Processors and Products

Compliance with this Standard demonstrates that the device is fit for purpose and can be used on a patient as it conforms to a range of relevant testing procedures. This information must be fulfilled by the manufacturers and processors and all test methods and results must be made available as part of a quality assurance system, for both single-use and reusable devices.

It should be noted that surgical drapes and gowns are further categorised according to their performance and defined as **standard** or **high performance** devices.

General requirements

The manufacturer or processor must:

- for reusable devices: provide information on the appropriate process to allow re-use (cleaning, disinfection, packaging, sterilisation methods) including number of re-uses and any restriction to the re-use
- for sterile devices: provide instructions for sterilization methods
- differentiate between critical and less critical areas on the device, where appropriate, as well as physical identification of these areas
- upon request, reference test methods used, and corresponding test results (see Tables 1, 2, and 3), differentiating critical and less critical areas with appropriate rationale for the differentiation
- use validated manufacturing and processing procedures

General product requirements:

- it shall be possible to demonstrate that the product requirements of EN 13795 are met (see Tables 4, 5 and 6), and test results shall be recorded and retained
- the finished product (after sterilisation if appropriate) shall be tested prior to commercialisation
- during manufacturing and processing, testing shall be done according to the requirements of the manufacturer's or processor's quality system

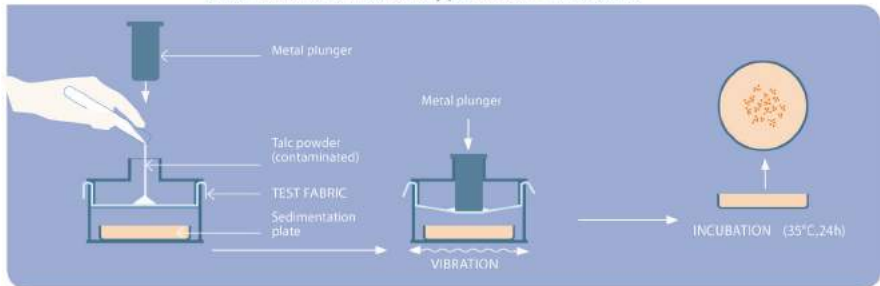


Key aspects of Annex B

Test Methods

EN 13795 describes the standardised and harmonised test methodologies that all single-use and reusable surgical drapes, gowns and clean air suits must undergo, as part of a quality assurance system.

Test of resistance to microbial dry penetration - EN ISO 22612



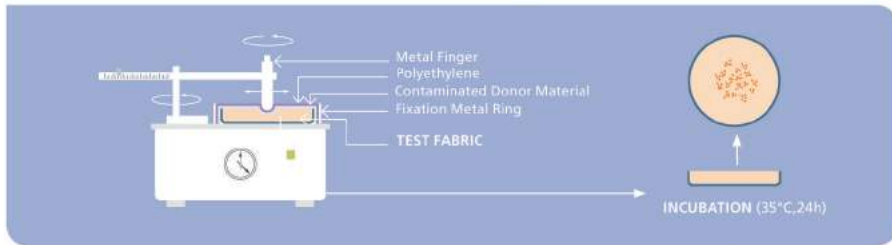
The test method is designed to determine the ability of materials to resist penetration of particles carrying micro-organisms under dry fabric conditions. The method establishes the quantity of micro-organisms that can penetrate through the test material being carried on talcum powder. Test results are expressed in CFU (colony forming units) that were observed on the agar plate.

Table 1 - Performance requirements for microbial dry penetration

Unit	Surgical Gowns				Surgical Drapes			
	Standard Performance		High Performance		Standard Performance		High Performance	
	critical area	less critical area	critical area	less critical area	critical area	less critical area	critical area	less critical area
CFU	N/A	≤ 300 *	N/A	≤ 300 *	N/A	≤ 300 *	N/A	≤ 300 *

a Test conditions: challenge concentration 10⁸ CFU/g talc, and 30 minutes vibration time.

Test of resistance to microbial wet penetration - EN ISO 22610



The purpose of this test is to evaluate the ability of fabrics to resist microbial penetration under conditions of liquid pooling on the fabric and mechanical stress. Test results are expressed in I_B "Barrier Index".

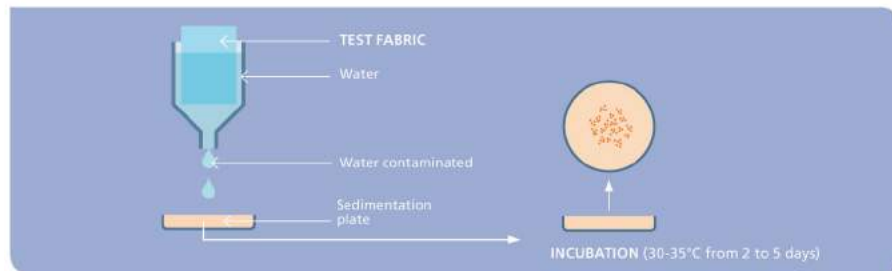
Table 2 - Performance requirements for microbial wet penetration

Unit	Surgical Gowns				Surgical Drapes			
	Standard Performance		High Performance		Standard Performance		High Performance	
	critical area	less critical area	critical area	less critical area	critical area	less critical area	critical area	less critical area
I_B	$\geq 2,8^b$	N/A	6,0 ^{b,c}	N/A	$\geq 2,8^b$	N/A	6,0 ^{b,c}	N/A

b The Least Significant Difference (LSD) for I_B when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. This means materials varying by up to 0,98 I_B are probably not different; materials varying by more than 0,98 I_B probably are different. (The 95% confidence level means that an observer would be correct 19 times out of 20 to accept these alternatives).

c $I_B = 6,0$ for the purpose of this standard means: no penetration. $I_B = 6,0$ is the maximum achievable value.

Test of microbial cleanliness - EN ISO 11737-1



Microbial cleanliness determines the bioburden, meaning the number of viable micro-organisms on the product.

Microbial cleanliness is especially important to achieve sterilisation and a sterilisation assurance level of 10^{-6} as is required to label a product as sterile.

For products that are not sold as sterile, the test method allows assessment of their potential for microbial contamination.

The test results are expressed in a decimal logarithm of CFU/100cm². Lower numbers indicate better cleanliness.

Table 3 - Performance requirements for microbial cleanliness

Unit	Surgical Gowns				Surgical Drapes			
	Standard Performance		High Performance		Standard Performance		High Performance	
	critical area	less critical area	critical area	less critical area	critical area	less critical area	critical area	less critical area
CFU/100 cm ²	≤ 300	≤ 300	≤ 300	≤ 300	≤ 300	≤ 300	≤ 300	≤ 300

Table 5 - Characteristics to be evaluated and Performance Requirements for Surgical Drapes

Performance requirements for Surgical Drapes						
Characteristic	Test method	Unit	Standard Performance		High Performance	
			Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration – dry	EN ISO 22612	CFU	N/A	≤ 300 ^a	N/A	≤ 300 ^a
Resistance to microbial penetration – wet	EN ISO 22610	I_b	≥ 2,8 ^b	N/A	6,0 ^{b,c}	N/A
Cleanliness – microbial	EN ISO 11737-1	CFU/100 cm ²	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness – particulate matter	EN ISO 9073-10	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	EN ISO 9073-10	log ₁₀ (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	EN 20811	cm H ₂ O	≥ 30	≥ 10	≥ 100	≥ 10
Bursting strength – dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength – wet	EN ISO 13938-1	kPa	≥ 40	N/A	≥ 40	N/A
Tensile strength – dry	EN 29073-3	N	≥ 15	≥ 15	≥ 20	≥ 20
Tensile strength – wet	EN 29073-3	N	≥ 15	N/A	≥ 20	N/A

a Test conditions: challenge concentration 10⁶ CFU/g talc, and 30 minutes vibration time.

b The Least Significant Difference (LSD) for I_b when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. This means materials varying by up to 0,98 I_b are probably not different; materials varying by more than 0,98 I_b probably are different. (The 95% confidence level means that an observer would be correct 19 times out of 20 to accept these alternatives).

c $I_b = 6,0$ for the purpose of this standard means: no penetration. $I_b = 6,0$ is the maximum achievable value.



Table 6 - Characteristics to be evaluated and performance requirements for Clean Air Suits

Performance requirements for Clean Air Suits			
Characteristic	Test method	Unit	Requirement ^a
Resistance to microbial penetration – dry	EN ISO 22612	CFU	≤ 300 ^a
Cleanliness – microbial	EN ISO 11737-1	CFU/100 cm ²	≤ 300
Cleanliness – particulate matter	EN ISO 9073-10	IPM	≤ 3,5
Linting	EN ISO 9073-10	log ₁₀ (lint count)	≤ 4,0
Bursting strength – dry	EN ISO 13938-1	kPa	≥ 40
Tensile strength – dry	EN 29073-3	N	≥ 20

a Test conditions: challenge concentration 10⁶ CFU/g talc, and 30 minutes vibration time.

b Performance requirements apply for all products areas of clean air suits.

WHY BROCHE NON WOVENS

The Safest Route is Impermeable (Laminated) Fabrics

Healthcare facilities face similar challenges :

- Improving efficiencies and ensuring patient safety

Many hospitals specifically mention improving efficiencies as a key challenge and ensuring patient safety as their main focus.

- Multiresistant bacteria

It is a well known fact that there is an increasing threat from multiresistant bacteria and that surgical site infections are very expensive for hospitals and society in general.

- Surgical site infections

In spite of high hygiene and asepsis standards, there are approximately three million healthcare-associated infections in the European Union each year. Not all of these infections are critical to the patient but they are all critical in the sense that they are painful for the individual and consume valuable hospital resources.



Some call it impermeable drapes.

We call it optimal safety.

- BROCHE NONWOVENS are dedicated to infection control in and around the operating room. We have always taken great pride in supplying healthcare facilities, all around the world, with products and solutions to ensure patient safety. Impermeable materials are always the safest choice, which is why BROCHE NONWOVENS has made the entire drape product range from impermeable.

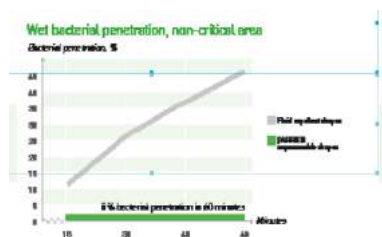
Why Impermeable (Laminated) Drapes?

When introduced, the fluid repellent single-use surgical drapes represented a real breakthrough in fabric technology. This material has served the global healthcare industry well, but as technology advances, we can now offer materials better suited to meet today's requirements.

No Compromises

Fluid repellent surgical drapes are vulnerable to liquid penetration despite meeting the standard EN13795. Today we know that fluid strikethrough can create a pathway for microorganisms, which can result in surgical site infections.

The wet bacterial penetration test shows that bacteria pass through a fluid repellent drape after 15 minutes of testing. The impermeable drape from BROCHE NONWOVENS showed no penetration of liquid and bacteria at all.



Fluid Repellent Surgical Drapes

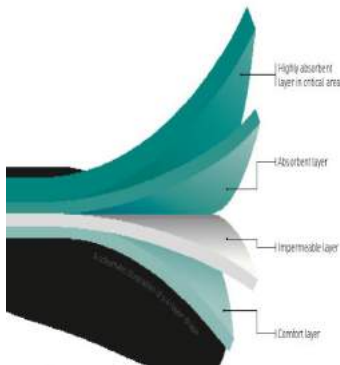
- Impermeable only in the critical area
- Vulnerable to liquid penetration, strikethrough, outside of the critical area
- Increased risk of bacterial and viral (as well as other microorganisms such as fungi and spores) penetration compared to impermeable drapes

Impermeable (Laminated) Surgical Drapes

- Impermeable throughout the drape
- Provide the highest level of protection possible in surgical drapes
- Always the safest choice

The safest draping material is impermeable

BROCHE NONWOVENS range of impermeable drapes covers all types of surgical interventions. The range is available in 1–4 ply materials, depending on the needs of the specific procedure.



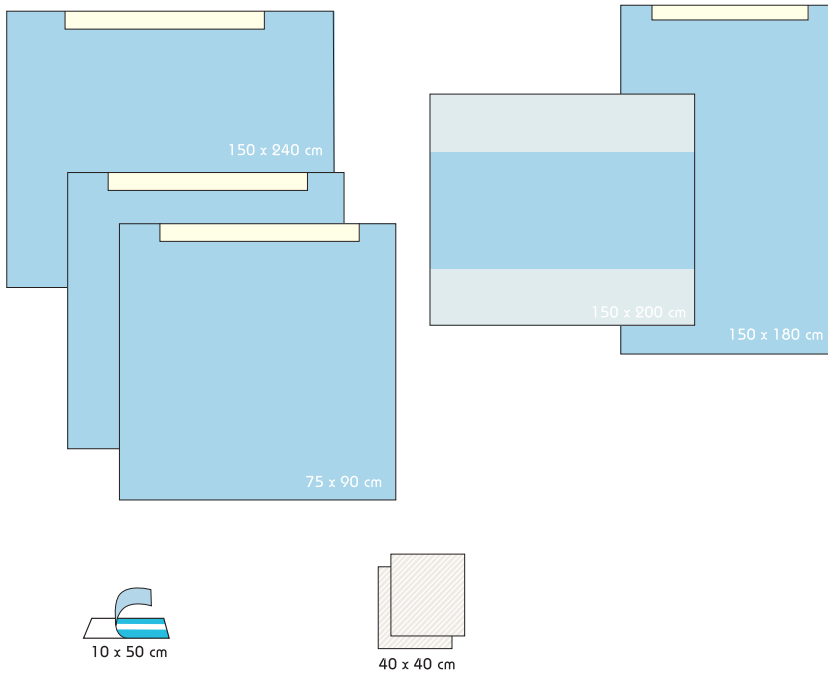
Why BROCHE NONWOVENS surgical drapes?

BROCHE NONWOVENS is dedicated to infection control. Overall improvements in design and material are part of the continuous work to always offer the safest choice.

- Comprehensive range of impermeable drapes available for all types of surgical interventions to fill all draping needs
- Continuous training and support to ensure optimised cost efficiencies and optimal usage of your products
- Introduction of new solutions when procedural needs change
- Supply and logistics system to ensure that the right products are available at the right time, spending a minimum of your resources.



General Surgery Pack - Standard

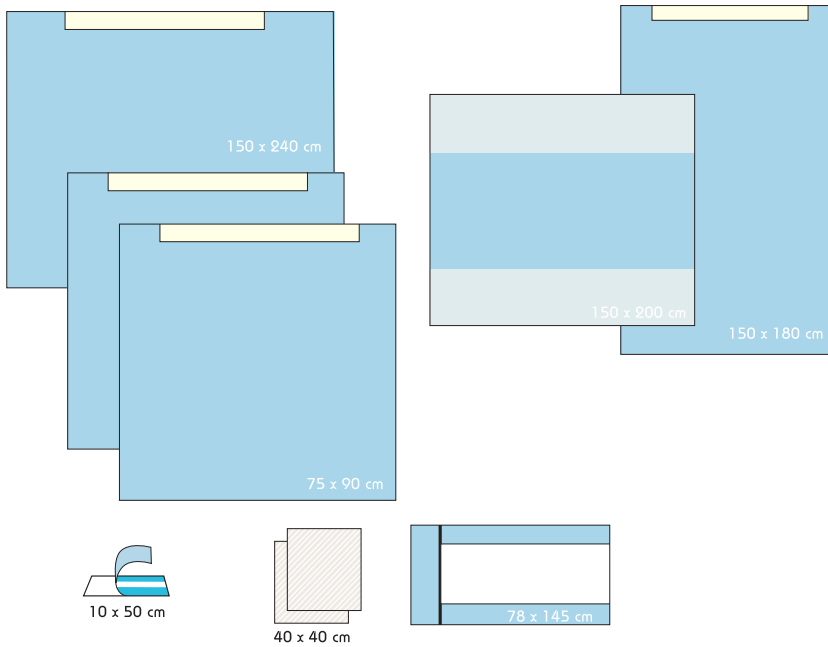


■ High Absorbent DL ■ SMS ■ PE Film ■ Adhesive Tape

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
ADS009	Anesthesia Drape	150 x 240 cm	1
ADS003	Adhesive Drape	75 x 90 cm	2
ADS008	Adhesive Drape	150 x 180 cm	1
OPS001	Op-Tapes	10 x 50 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

General Surgery Pack - Large

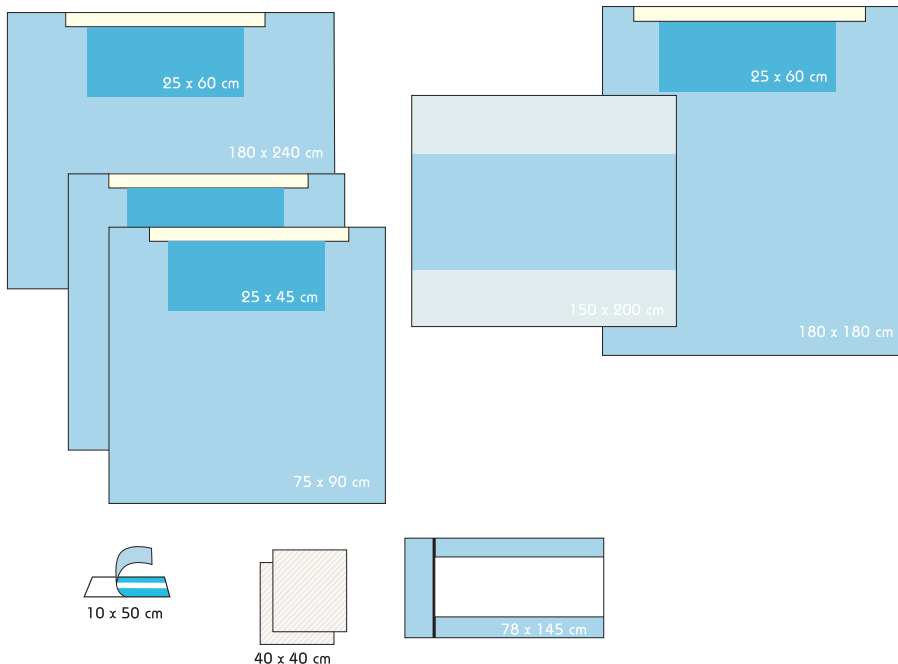


■ High Absorbent DL
 ■ SMS
 ■ PE Film
 ■ Adhesive Tape

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
MYS001	Mayo Stand Cover	78 x 145 cm	1
ADS009	Anesthesia Drape	150 x 240 cm	1
ADS003	Adhesive Drape	75 x 90 cm	2
ADS008	Adhesive Drape	150 x 180 cm	1
OPS001	Op-Tapes	10 x 50 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

General Surgery Pack - Extra Large

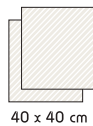
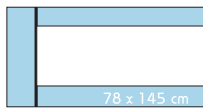
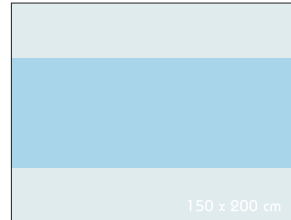
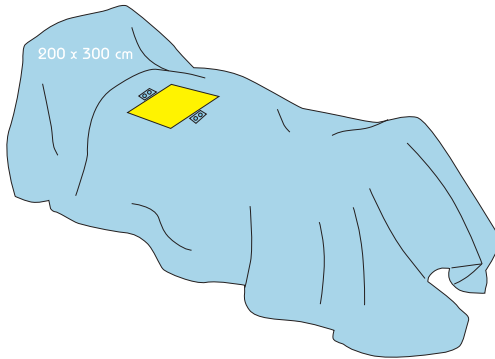


■ High Absorbent DL ■ SMS ■ Extra Absorbent ■ PE Film ■ Adhesive Tape

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
MYS001	Mayo Stand Cover	78 x 145 cm	1
ADS0011	Anesthesia Drape, Extra Absorbing 25x60 cm	180 x 240 cm	1
ADS003	Adhesive Drape, Extra Absorbing 25x45 cm	75 x 90 cm	2
ADS010	Adhesive Drape, Extra Absorbing 25x60 cm	180 x 180 cm	1
OPS001	Op-Tapes	10 x 50 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Laparoscopy Pack

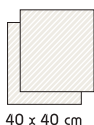
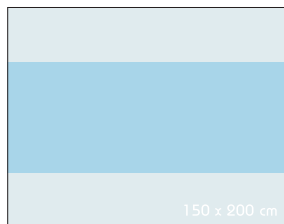
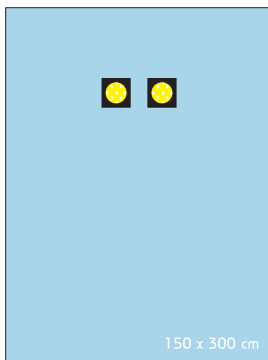


High Absorbent DL
 SMS
 PE Film
 Inscice Film
 Adhesive Tape

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
MYS001	Mayo Stand Cover	78 x 145 cm	1
LDS001	Laparoscopy Drape, aperture 25x30 cm	200 x 300 cm	1
OPS001	Op-Tapes	10 x 50 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Angiography Pack - Standard

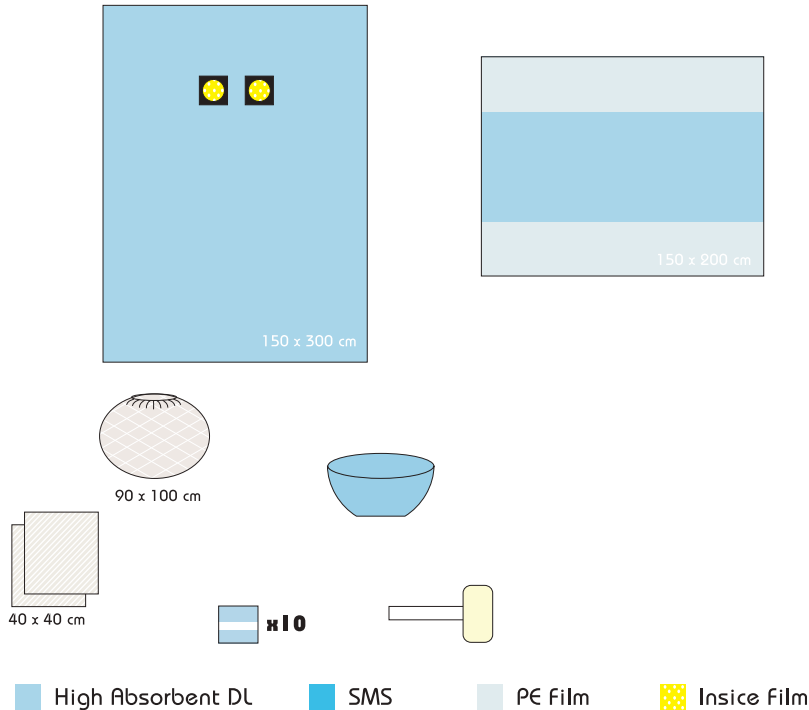


High Absorbent DL
 SMS
 PE Film
 Insize Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
APS002	Angiography Drape, apertures 9 cm	150 x 300 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

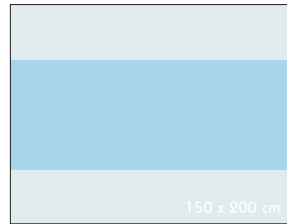
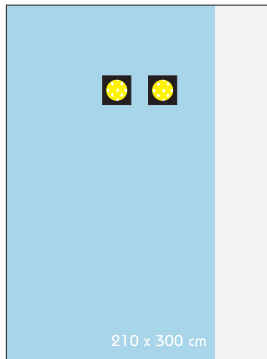
Angiography Pack - Large



Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
APS002	Angiography Drape, apertures 9 cm	150 x 300 cm	1
FSC001	Fluoroscopy Cover, PVC	90 x 100 cm	1
BSS001	Betadine Sponge	ST	1
SCS001	Solution Cup	500 cc	1
GSS001	Gauze Swabs	7,5 x 7,5 cm	10
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Angiography Pack W / Transparent Panel Standard

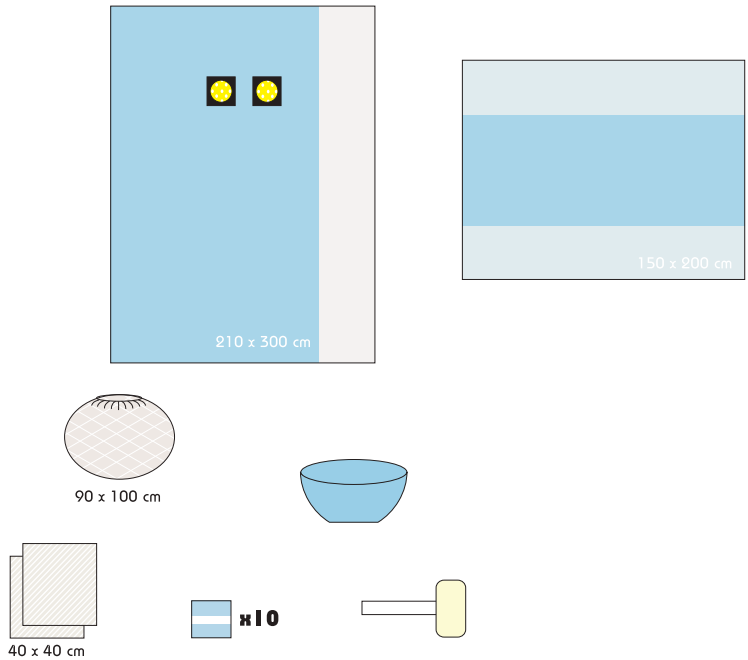


High Absorbent DL
 SMS
 PE Film
 Insize Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
APS001	Angiography Drape With Transparent Panel, apertures 9 cm	210 x 300 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Angiography Pack W / Transparent Panel Large

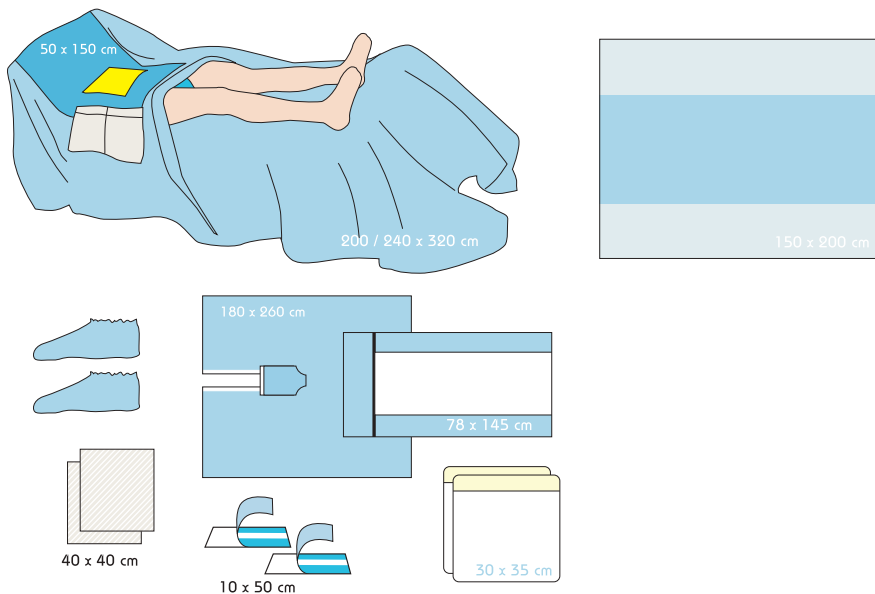


High Absorbent DL
 SMS
 PE Film
 Inscise Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
APS001	Angiography Drape With, Transparent Panel, apertures 9 cm	210 x 300 cm	1
FCS001	Fluoroscopy Cover, PVC	90 x 100 cm	1
SCS001	Solution Cup	500 cc	1
BSS001	Betadine Sponge	ST	1
GSS001	Gauze Swabs	7,5 x 7,5 cm	10
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Cardiovascular Pack W / Pouch - Standard

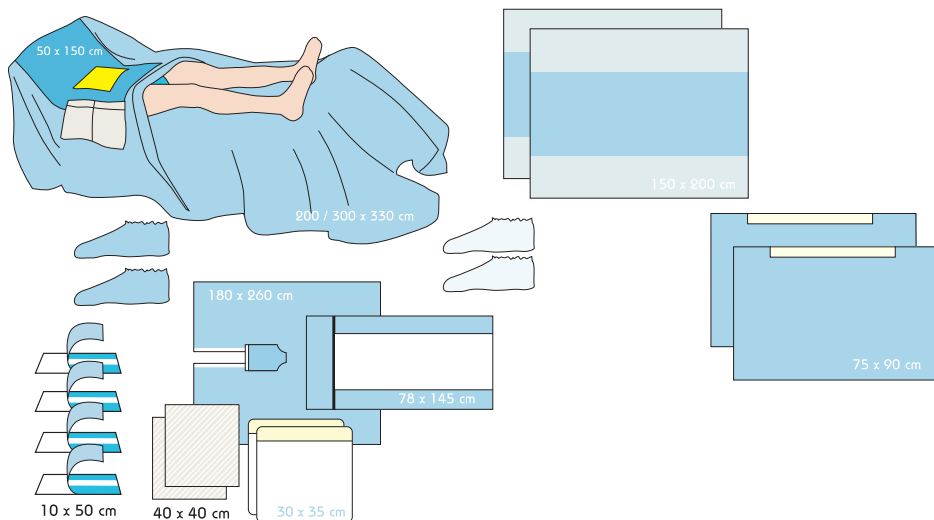


■ High Absorbent DL
 ■ Super Absorbent DL
 ■ SMS
 ■ PE Film
 ■ Insice Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
MYS001	Mayo Stand Cover	78 x 145 cm	1
UDS003	U Split Perineal Drape, aperture 20 x 100 cm	180 x 260 cm	1
CVS002	Cardiovascular Drape, extra absorbing area 50 x 150 cm	200/240 x 320 cm	1
FSS001	Feet Socks	ST	2
OPS001	Op Tapes	10 x 50 cm	2
MPS001	Mobile PVC Bag	30 x 35 cm	2
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Cardiovascular Pack W / Pouch - Large

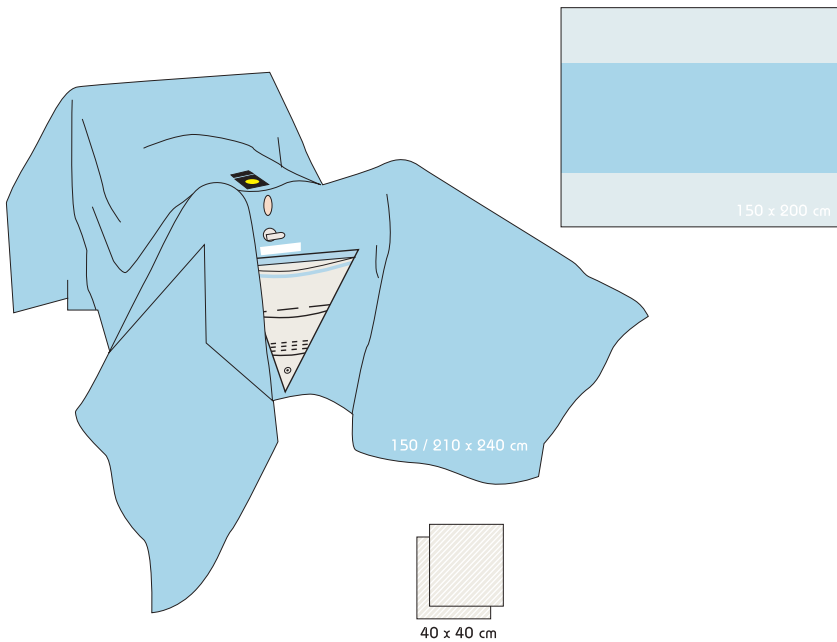


■ High Absorbent DL
 ■ Super Absorbent DL
 ■ SMS
 ■ PE Film
 ■ Insice Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	2
MYS001	Mayo Stand Cover	78 x 145 cm	1
UDS003	U Split Perineal Drape, aperture 20 x 100 cm	180 x 260 cm	1
CVS002	Cardiovascular Drape, aperture 32 x 40 cm	200/300 x 330 cm	1
FSS001	Feet Socks	ST	2
FSS002	Feet Socks	Transparent	2
ADS003	Adhesive Drape	75 x 90 cm	2
OPS001	Op Tapes	10 x 50 cm	4
MPS001	Mobile PVC Bag	30 x 35 cm	2
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Tur Pack W / Pouch (Urology Set)



■ High Absorbent DL

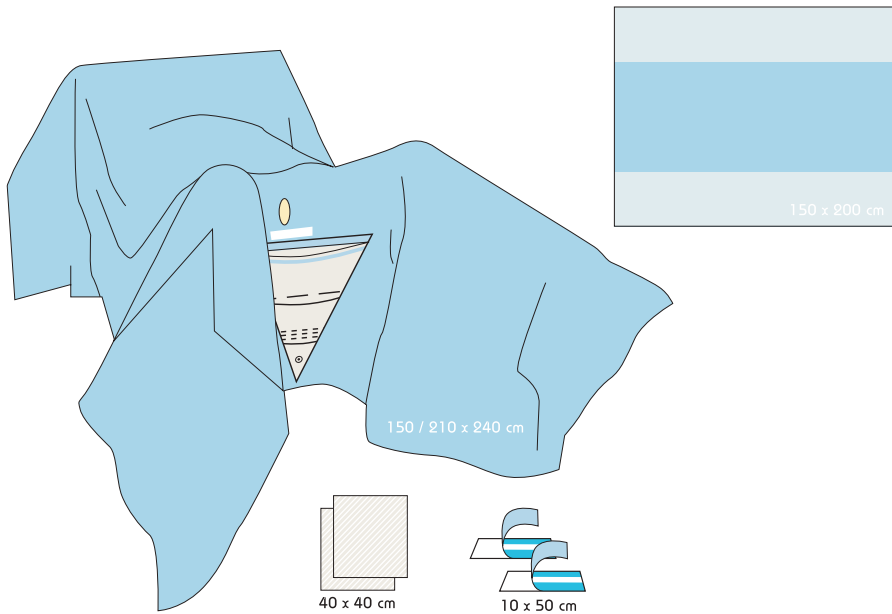
■ SMS

■ PE Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
UDS001	Urology Drape W / Pouch, apertures 8 cm and 5 cm	150 / 210 x 240 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Lithotomic Gynaecology Pack W / Pouch



■ High Absorbent DL

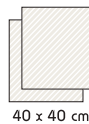
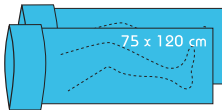
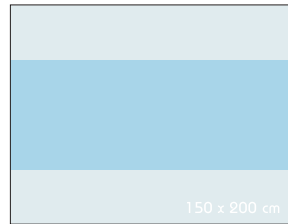
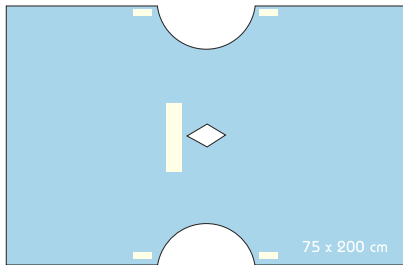
■ SMS

■ PE Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
UDS001	Lithotomic Gynaecology W / Pouch apertures 10 x 15 cm	150 / 210 x 240 cm	1
OPS001	Op-Tapes	10 x 50 cm	2
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Gynaecology / Cystoscopy Pack

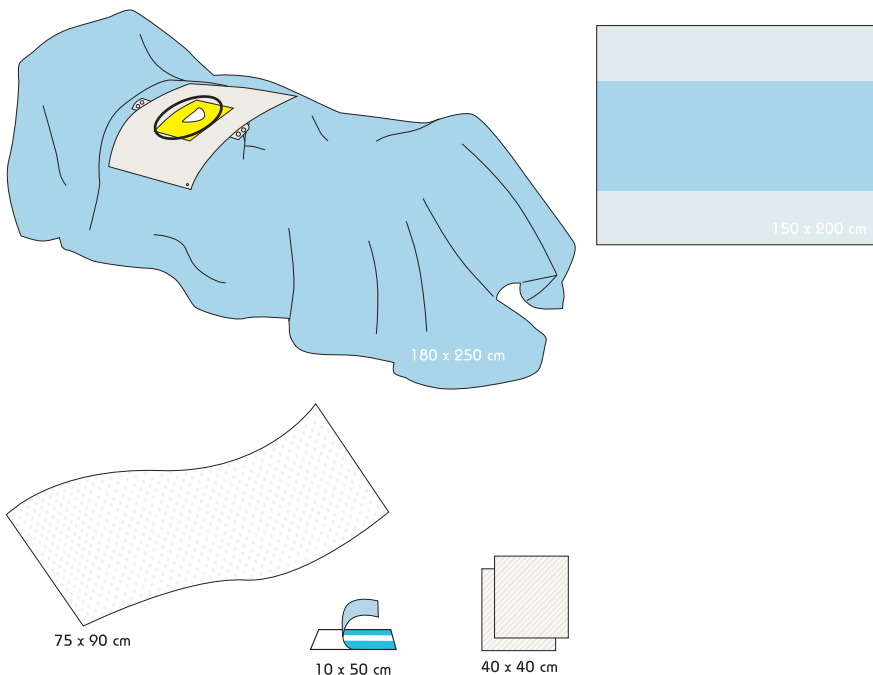


High Absorbent DL
 SMS
 PE Film
 Adhesive Tape

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
CDS001	Cystoscopy Drape W / Adhesive Tape, apertures 10 x 15 cm	75 x 200 cm	1
LGS001	Leggings	75 x 120 cm	2
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Caesarean Section Pack W / Pouch - Standard

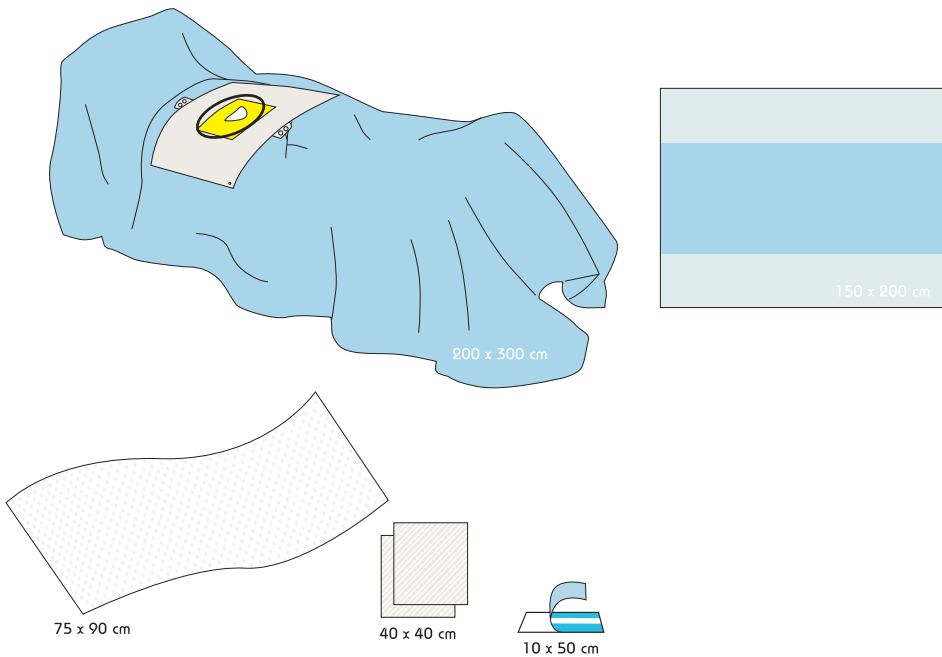


High Absorbent DL
 SMS
 PE Film
 Inscie Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
CES001	Caesarean Drape W / Pouch apertures 32 x 38 cm	180 x 250 cm	1
BBS001	Baby Blanket	75 x 90 cm	1
OPS001	Op-Tapes	10 x 50 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Caesarean Section Pack W / Pouch - Large

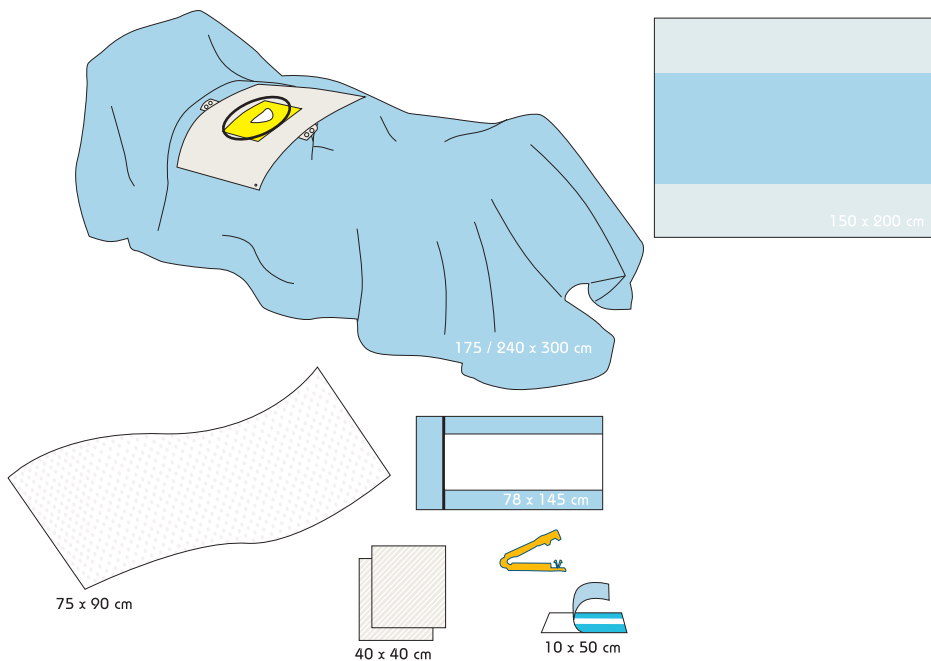


High Absorbent DL
 SMS
 PE Film
 Inscie Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
CES002	Caesarean Drape W / Pouch apertures 38 x 32 cm	200 x 300 cm	1
BBS001	Baby Blanket	75 x 90 cm	1
OPS001	Op-Tapes	10 x50 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Caesarean Section Pack W / Pouch - Extra Large

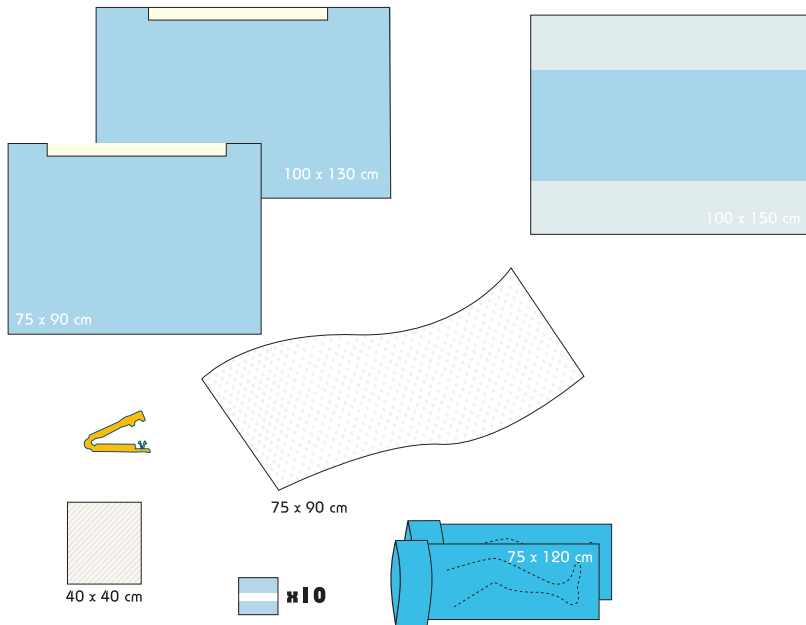


High Absorbent DL
 SMS
 PE Film
 Inscise Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
MYS001	Mayo Stand Cover	78 x 145 cm	1
CES003	Caesarean Drape W / Pouch apertures 38 x 32 cm	175 / 240 x 300 cm	1
BBS001	Baby Blanket	75 x 90 cm	1
CLP001	Umbilical Clamp	ST	1
OPS001	Op-Tapes	10 x50 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Delivery Pack

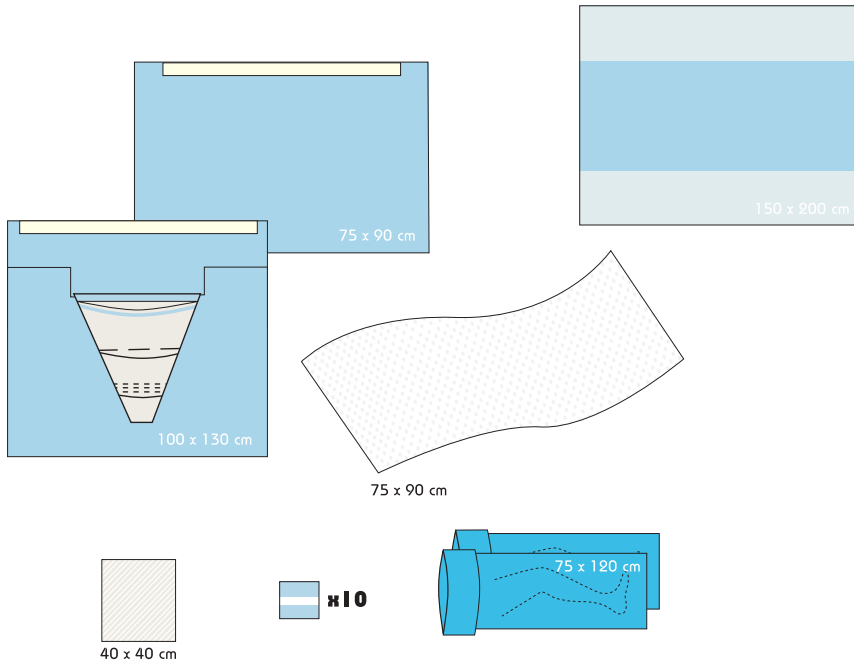


High Absorbent DL
 SMS
 PE Film
 Adhesive Tape

Codes	Description	Dimension	Quantity
ITS001	Instrument Table Cover	100 x 150 cm	1
UDS002	Underbuttock Drape	100 x 130 cm	1
ADS003	Abdominal Drape W / Adhesive Tape	75 x 90 cm	1
LGS002	Leggings	75 x 120 cm	2
CLP001	Umbilical Clamp	ST	1
BBS001	Baby Blanket	75 x 90 cm	1
GSS001	Gauze Swabs	7,5 x 7,5 cm	10
HTS001	Hand Towels	40 x 40 cm	1

*Product contents can be customized upon request

Delivery Pack W / Pouch

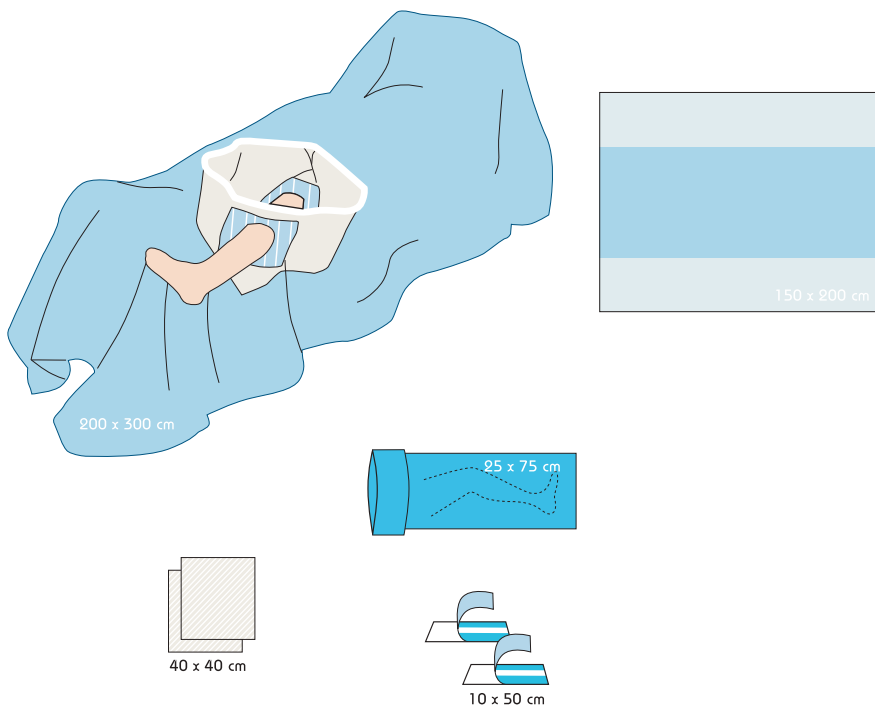


High Absorbent DL
 SMS
 PE Film
 Adhesive Tape

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
UDS005	Underbuttock Drape W / Pouch	100 x 130 cm	1
ADS003	Abdominal Drape W / Adhesive Tape	75 x 90 cm	1
LGS002	Leggings	75 x 120 cm	2
BBS001	Baby Blanket	75 x 90 cm	1
GSS001	Gauze Swabs	7,5 x 7,5 cm	10
HTS001	Hand Towels	40 x 40 cm	1

*Product contents can be customized upon request

Arthroscopy Pack W / Pouch - Standard

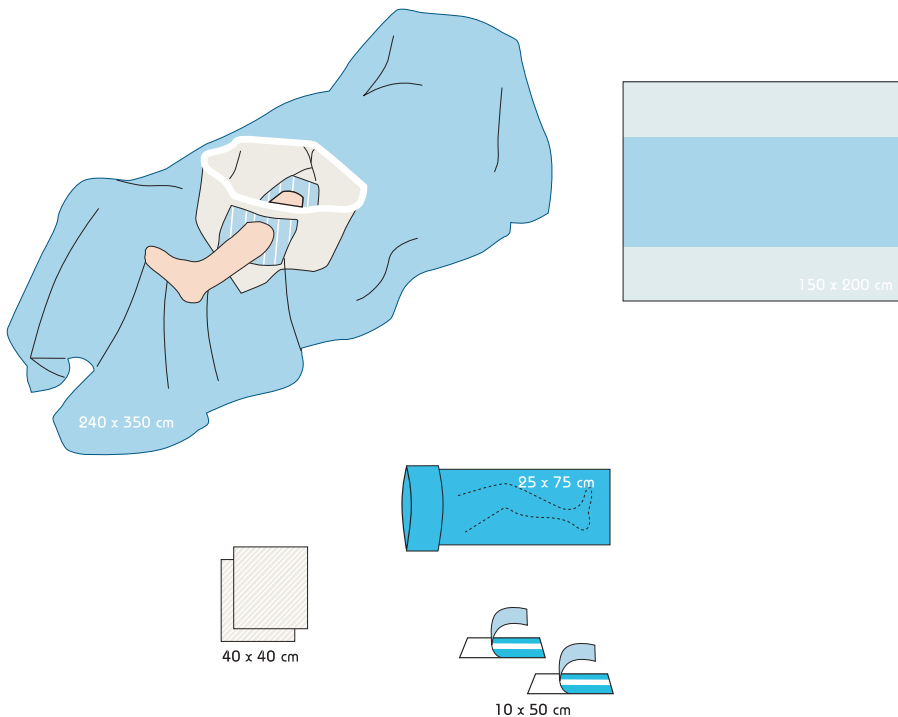


High Absorbent DL
 SMS
 PE Film
 Inside Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
ATS001	Arthroscopy Drape W / Pouch, apertures 6 cm	200 x 300 cm	1
SSS001	Stockinet	25 x 75 cm	1
OPS001	Op-Tapes	10 x 50 cm	2
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Arthroscopy Pack W / Pouch - Large

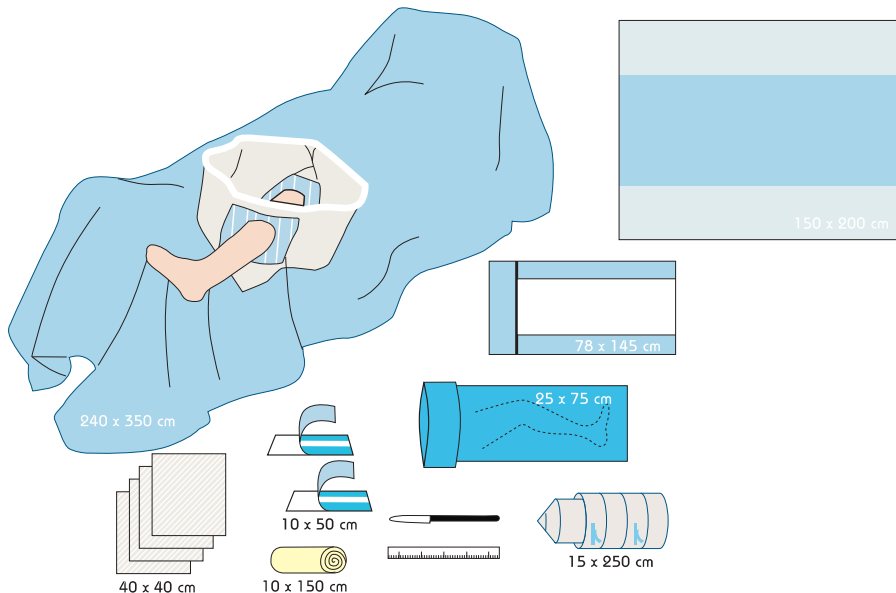


High Absorbent DL
 SMS
 PE Film
 Inside Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
ATS001	Arthroscopy Drape W / Pouch, apertures 6 cm	240 x 350 cm	1
SSS001	Stockinet	25 x 75 cm	1
OPS001	Op-Tapes	10 x 50 cm	2
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Arthroscopy Pack W / Pouch - Extra Large

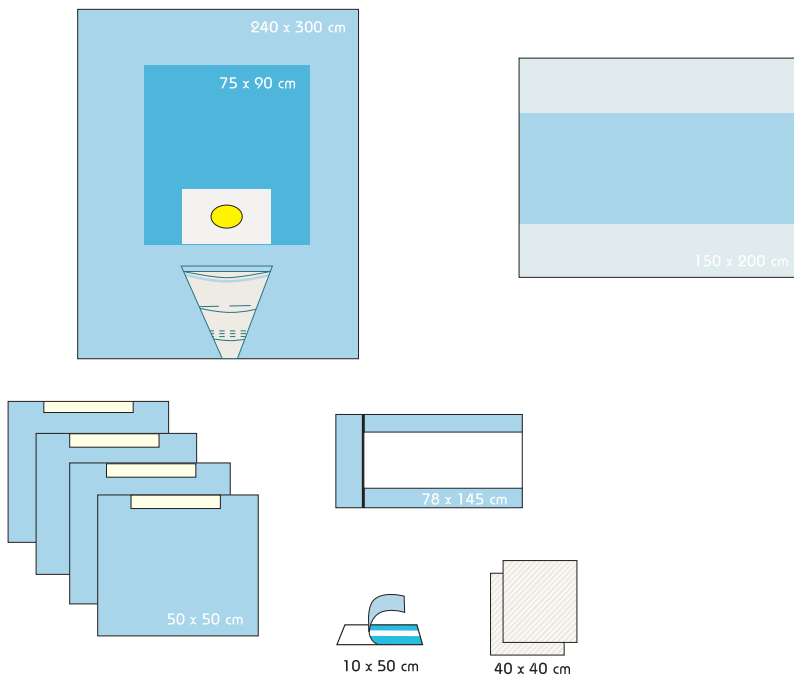


High Absorbent DL
 SMS
 PE Film
 Insice Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
MYS001	Mayo Stand Cover	78 x 145 cm	1
ATS002	Arthroscopy Drape W / Pouch, apertures 6 cm	240 x 350 cm	1
CCS001	Camera Cover	15 x 250 cm	1
SMS001	Skin Marker and Ruler	ST	1
€BS001	Elastic Bandage	10 x 150 cm	1
SSS001	Stockinet	25 x 75 cm	1
OPS001	Op-Tapes	10 x 50 cm	2
HTS001	Hand Towels	40 x 40 cm	4

*Product contents can be customized upon request

Craniotomy Pack W / Pouch

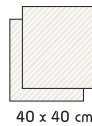
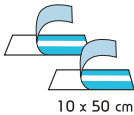
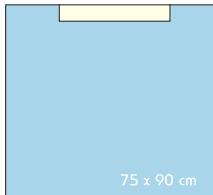
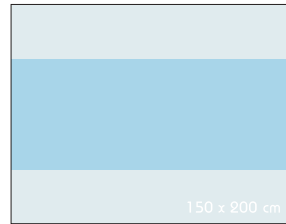
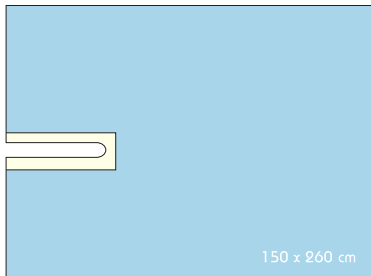


■ High Absorbent DL
 ■ Super Absorbent DL
 ■ SMS
 ■ PE Film
 ■ Adhesive Tape

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
MYS001	Mayo Stand Cover	78 x 145 cm	1
CTS001	Craniotomy Drape W / Pouch, aperture 20 x 30 cm, extra absorbing area 75 x 90 cm	240 x 300 cm	1
ADS001	Adhesive Drape	50 x 50 cm	4
OPS001	Op-Tapes	10 x 50 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

E.N.T. Pack



■ High Absorbent DL

■ SMS

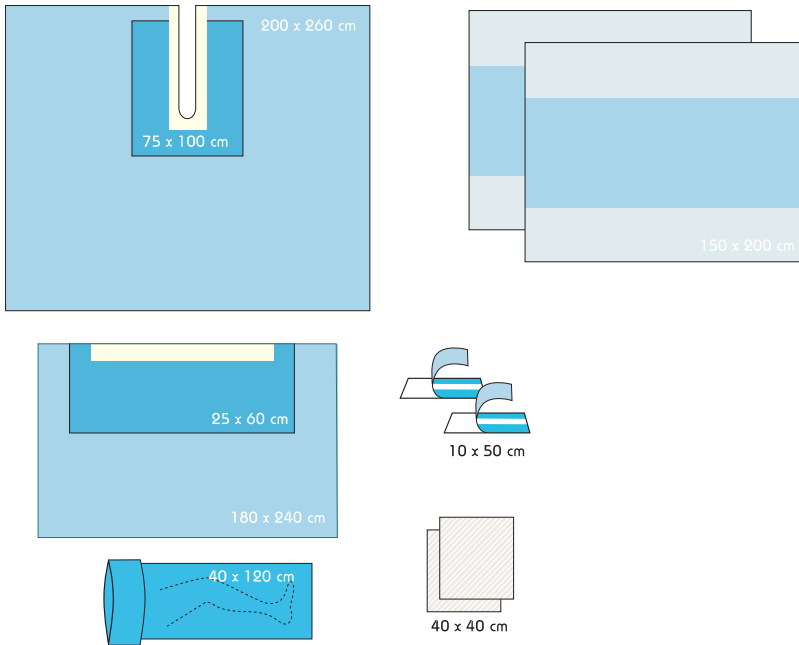
■ PE Film

■ Inside Film

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	1
MYS001	Mayo Stand Cover	78 x 145 cm	1
UDS004	U Split Drape, aperture 7 x 70 cm	150 x 260 cm	1
ADS003	Adhesive Drape	75 x 90 cm	1
OPS001	Op-Tapes	10 x 50 cm	2
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Hip Pack U

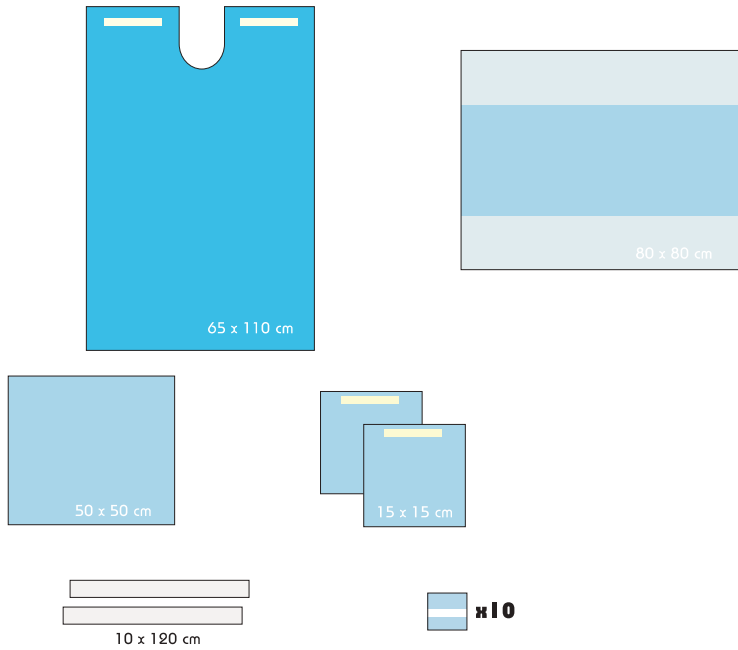


■ High Absorbent DL
 ■ Super Absorbent DL
 ■ SMS
 ■ PE Film
 ■ Adhesive Tape

Codes	Description	Dimension	Quantity
ITS003	Instrument Table Cover	150 x 200 cm	2
UDS006	U Split Drape, aperture 20 x 100 cm, extra absorbing area 75 x 100 cm	200 x 260 cm	1
ADS011	Adhesive Drape, extra absorbing area 25 x 60 cm	180 X 240 cm	1
LGS003	Leggings	40 x 120 cm	1
OPS001	Op-Tapes	10 x 50 cm	2
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

Implant Pack

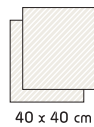
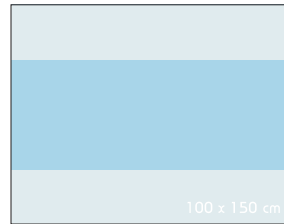
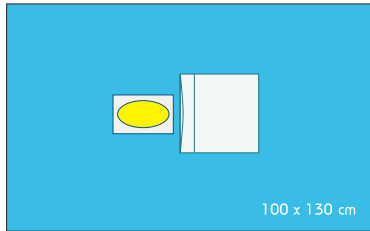


High Absorbent DL
 SMS
 PE Film
 Adhesive Tape

Codes	Description	Dimension	Quantity
ITS002	Instrument Table Cover	80 x 80 cm	1
DPS001	Dental Patient Gown W / Velcro	65 x 110 cm	1
TDS001	Table Drape	50 x 50 cm	1
RDS001	Reflector Drape	15 x 15 cm	2
THS001	Transparent Hose Cover	10 x 120 cm	2
GSS001	Gauze Swabs	7,5 x 7,5 cm	10

*Product contents can be customized upon request

Single Pouch Ophthalmic Pack



■ SMS

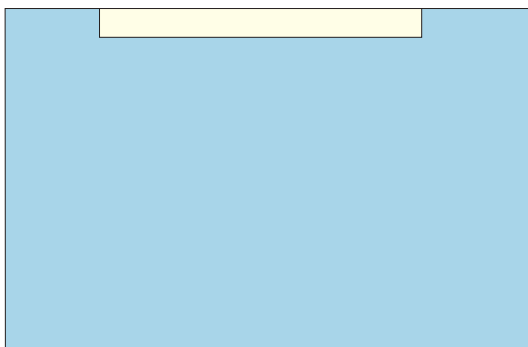
■ PE Film

■ Insize Film

Codes	Description	Dimension	Quantity
ITS001	Instrument Table Cover	100 x 150 cm	1
ODS001	Single Pouch Ophthalmic Drape W / Pouch, aperture 10 x 10	100 x 130 cm	1
HTS001	Hand Towels	40 x 40 cm	2

*Product contents can be customized upon request

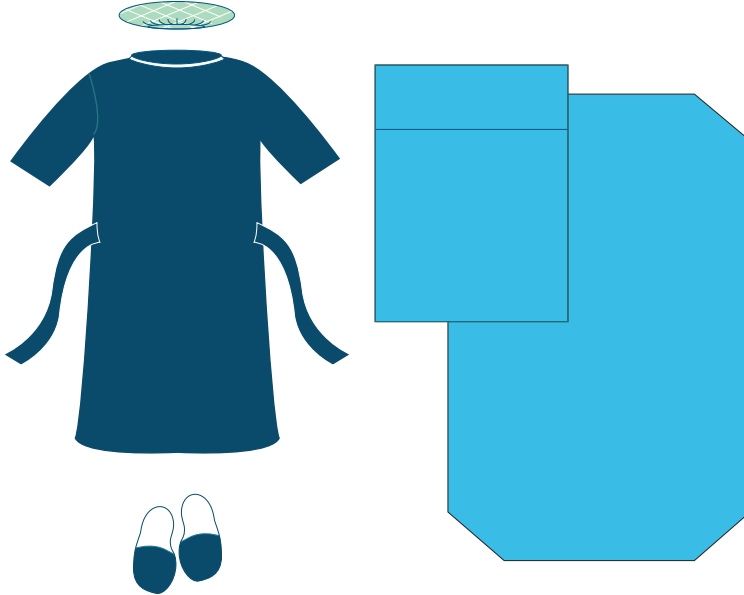
Adhesive Drapes



■ High Absorbent DL □ Adhesive Tape

Sterile Codes	Description	Dimension
ADS001	Adhesive Drape	50 x 50 cm
ADS002	Adhesive Drape	75 x 75 cm
ADS003	Adhesive Drape	75 x 90 cm
ADS004	Adhesive Drape	75 x 150 cm
ADS005	Adhesive Drape	100 x 100 cm
ADS006	Adhesive Drape	120 x 150 cm
ADS007	Adhesive Drape	120 x 240 cm
ADS008	Adhesive Drape	150 x 180 cm
ADS009	Adhesive Drape	150 x 240 cm
ADS010	Adhesive Drape	180 x 180 cm
ADS011	Adhesive Drape	180 x 240 cm

Non Sterile Welcome Pack (Waterproof)



■ PP

■ SMS

Codes	Description	Dimension	Quantity
BCNS001	Bed Cover W / Elastic Edges	160 x 240 cm	1
PCNS001	Pillow Cover	50 x 70 cm	1
SLPNS	Slippers	ST	1
PGNSS001	Patient Gown Short Sleeve	LARGE	1
SBCNS001	Soft Bar Caps	ST	1

Product Code Without Gown

WPNS001 - NG

*Product contents can be customized upon request



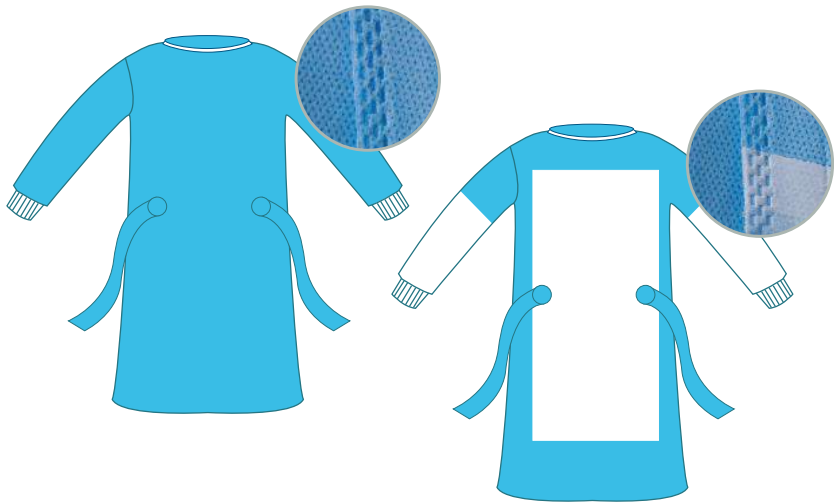
Broche[®] Gowns





STERILE GOWNS

Disposable Sterile Ultrasonic Stitch Surgical Gown



COLOR



BLUE

DESCRIPTION	SIZE	CODE
SMS/SMWMS STERILE ULTRASONIC STITCH STANDARD SURGICAL GOWN W/A TOWEL	L - XL	SGC001 - SGC002
SMS/SMWMS STERILE ULTRASONIC STITCH REINFORCED SURGICAL GOWN W/A TOWEL	L - XL	RG001 - RG002

GOWNS DETAILS

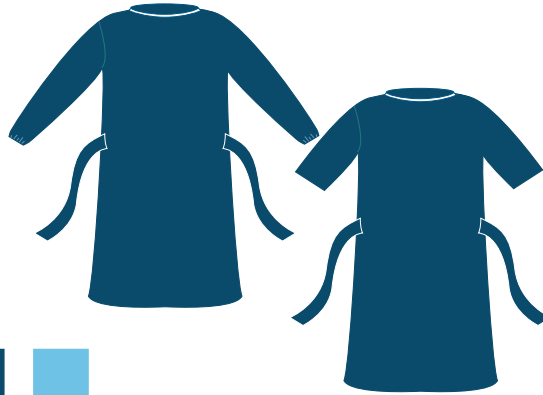
The surgical gowns are sterilized with ethylenoxide and are designed to cover the surgeon during surgical operations. The gowns are classified into two types according to the duration of the surgical operations and also according to the type of selected material - SMS/SMWMS - and each of them may be equipped with liquid resistant lining. The elastic cuff on the sleeves are made from 95% cotton, 5% spandex.

- Water resistant
- Easy fit
- Comfortable design
- Air permeable
- Ultrasonic stitch

Gowns have the quality to allow respiration, and retain and repel alcohol, blood, water and any kind of body fluids without absorbing them. Gowns, which are produced with no-shred and non-woven SMS/SMWMS fabric, do not let soaking up, thus, prevents infection spread, and provide a healthy and comfortable work environment for medical personnel.

NON-STERILE GOWNS

Disposable Non-Sterile Patient Gown



COLOR



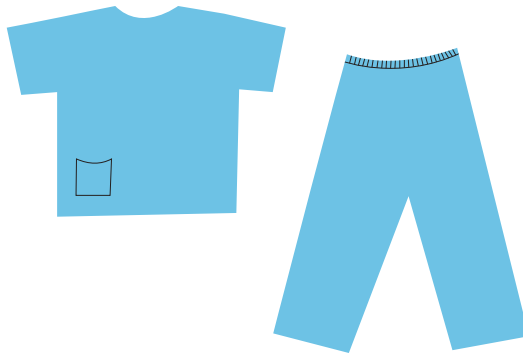
NAVY



BLUE

DESCRIPTION	SIZE	CODE
NON-STERILE PATIENT GOWN (LONG SLEEVE)	L - XL	PGL001 - PGL002
NON-STERILE PATIENT GOWN (SHORT SLEEVE)	L - XL	PGS001 - PGS002

Disposable Non-Sterile Doctor Scrub Suits



COLOR



BLUE

DESCRIPTION	SIZE	CODE
NON-STERILE DISPOSABLE DOCTOR SCRUB SUITS	L - XL	DSS001 - DSS002



Broche[®] *Gloves*



STERILE GLOVES

Chloroprene Synthetic Sterile Surgical Gloves **NEO+PLUS**



DESCRIPTION

POWDER FREE

LATEX FREE, NON-ALLERGIC

BEADED CUFF

FOR SINGLE USE ONLY

50 PAIRS PER BOX

AQL 1,5

STERILE **R**

SIZE

6,5 - 7 - 7,5 - 8 - 8,5

COLOR



BROWN

STERILE GLOVES

Latex Sterile Surgical Gloves **+PLUS**



DESCRIPTION

POWDERED and POWDER FREE
BEADED CUFF
TEXTURED
WEIGHT REFERENCE SIZE 7,5: 16,8 gr/pair
FOR SINGLE USE ONLY
50 PAIRS PER BOX
AQL 1,5
STERILE **R**

SIZE

6,5 - 7 - 7,5 - 8 - 8,5

COLOR



NATURAL

NON-STERILE GLOVES

Latex Examination Gloves



DESCRIPTION

POWDERED
SMOOTH SURFACE
BEADED CUFF
AMBIDEXTROUS
FOR SINGLE USE ONLY
100 PCS PER BOX

SIZE

XS - S - M - L

COLOR



NATURAL



NON-STERILE GLOVES

Latex Examination Gloves



DESCRIPTION

POWDER FREE

TEXTURED

BEADED CUFF

AMBIDEXTROUS

FOR SINGLE USE ONLY

100 PCS PER BOX

SIZE

S - M - L

COLOR



NATURAL



NON-STERILE GLOVES

Vinyl Examination Gloves



DESCRIPTION

POWDERED
LATEX FREE
BEADED CUFF
AMBIDEXTROUS
FOR SINGLE USE ONLY
100 PCS PER BOX
AQL 1,5

SIZE

S - M - L

COLOR



CLEAR

NON-STERILE GLOVES

Vinyl Examination Gloves



DESCRIPTION

POWDER FREE
LATEX FREE
BEADED CUFF
AMBIDEXTROUS
FOR SINGLE USE ONLY
100 PCS PER BOX
AQL 1,5

SIZE

S - M - L

COLOR



NON-STERILE GLOVES

Nitrile Examination Gloves



DESCRIPTION

POWDER FREE
LATEX FREE, NON ALLERGIC
FINGER TEXTURED
BEADED CUFF
AMBIDEXTROUS
FOR SINGLE USE ONLY
100 PCS PER BOX
AQL 1,5

SIZE

S - M - L

COLOR



NON-STERILE GLOVES

Nitrile Chemotherapy Examination Gloves



DESCRIPTION

POWDER FREE
LATEX FREE, NON ALLERGIC
TESTED FOR USE WITH CHEMOTHERAPY DRUGS
4 MIL - 12" CUFF
FINGER TEXTURED
BEADED CUFF
AMBIDEXTROUS
FOR SINGLE USE ONLY
100 PCS PER BOX
AQL 1,5

SIZE

S - M - L

COLOR



BLUE



NON-STERILE GLOVES

PE Gloves



DESCRIPTION

FOR SINGLE USE ONLY

WEIGHT 7 KG / 10.000 pcs

100 PCS PER BAG

SIZE

L

COLOR



CLEAR

Broche[®] *Plastic Products*



PLASTIC PRODUCTS

Sterile Flowmeter



DESCRIPTION	DESCRIPTION
MATERIAL: MEDICAL GRADE POLY VINYL CHLORIDE	LUER LOCK
DROPPING VARIATION 5 TO 250 ML/h	FOR SINGLE USE ONLY
LATEX FREE	INDIVIDUAL PACKING
∇ INJECTION PORT	EO STERILE

Sterile Infusion (Serum) Set



DESCRIPTION	DESCRIPTION
MATERIAL: MEDICAL GRADE POLY VINYL CHLORIDE	WITH AIR VENT
WITH DRAIN CHAMBER	FOR SINGLE USE ONLY
APPROPRIATE FOR INFUSION BOTTLES AND ALSO FOR INFUSION BAGS	INDIVIDUALLY PACKED IN PE BAG
FILTER IN DRAIN CHAMBER	EO STERILE
WITH A FLOW REGULATOR	

PLASTIC PRODUCTS

Sterile Urine Bag / T-Valve and Push & Pull Valve



DESCRIPTION

MATERIAL: MEDICAL GRADE PVC

2000 ML COLLECTING CAPACITY

WITH ANTI-REFLUX VALVE

REINFORCED HOLES FOR HANGING

LATEX FREE

FOR SINGLE USE ONLY

INDIVIDUALLY PACKED IN PE BAG

EO STERILE

PLASTIC PRODUCTS

Sterile Blood Transfusion Set



DESCRIPTION

MATERIAL: MEDICAL GRADE POLY VINYL CHLORIDE

WITH FLOW REGULATOR

WITH BLOOD FILTER

NON TOXIC and NON PYROGENIC

18 G HYPODERMIC NEEDLE

WITH AIR VENT

FOR SINGLE USE ONLY

INDIVIDUALLY PACKED IN PE BAG

EO STERILE

Broche[®] *Medical Disposables*



MEDICAL DISPOSABLES

Sterile Surgical Blades



DESCRIPTION

MATERIAL: CARBON STEEL

NO: 10 - 11 - 12 - 15 - 18 - 20 - 21 - 22 - 23 - 24 - 25

FOR SINGLE USE ONLY

100 PCS PER BOX

STERILE 



MEDICAL DISPOSABLES

Sterile Blood Lancet



DESCRIPTION

MATERIAL: CARBON STEEL

DISPOSABLE

FOR SINGLE USE ONLY

200 Pcs PER BOX

STERILE **R**



MEDICAL DISPOSABLES

Sterile / Non-Sterile Wooden Tongue Depressor



DESCRIPTION

MATERIAL: BIRCH TREE

SMOOTH SURFACE WITH ROUND ENDS

FOR SINGLE USE ONLY

100 PCS PER BOX

SIZE

ADULT 150mm X 18mm

MEDICAL DISPOSABLES

Shoe Covers



DESCRIPTION

MATERIAL: POLYETHYLENE
FOR SINGLE USE ONLY
100 PCS PER PACKET

COLOR



BLUE

MEDICAL DISPOSABLES

Face Mask



DESCRIPTION

MATERIAL: NONWOVEN POLYPROPYLENE SPUNBONDED FABRIC

2 PLY AND 3 PLY

ULTRASONIC STITCH

WITH ROUND ELASTIC EARLOOP OR WITH POLYPROPYLENE TIE

NOSE SUPPORT

FOR SINGLE USE ONLY

50 PCS PER BOX

COLOR



MEDICAL DISPOSABLES

Soft Bar Cap



DESCRIPTION	SIZE
MATERIAL: NONWOVEN POLYPROPYLENE SPUNBONDED FABRIC	21 INCH
ULTRASONIC STITCH	
DOUBLE ELASTIC	
FOR SINGLE USE ONLY	
100 PCS PE BAG	

COLOR



GREEN



WHITE

SZUTEST

EC CERTIFICATE AT SERTİFİKA

According to Annex II of the Directive 93/42/EEC on Medical Devices
93/42/AT Tıbbi Cihaz Yönetmeliği Ek II'ye göre

Full Quality Assurance System
Tam Kalite Güvencesi

Certificate Number: 2195-MED-1412002
Sertifika Numarası

Manufacturer: Nurtexs Tekstil ve Medikal Sanayi Dış Ticaret Anonim Şirketi
Üretici
Head Office: Kışklı Çeşme Mah. Yeni Bağdat Cad. No:124 Gebze / Kocaeli
/Merkez: Türkiye
Branch Office: Oruç Reis Mah. Tekstilcent Cad. Tekstilcent Sitesi B Blok
/Şube: No:12A Kapı No:031 ve 034 Esenler / İstanbul Türkiye

Product(s): Sterile Disposable Surgical Drape, Gown and Drape Sets
Ürün(ler)
Steril Tek Kullanımlık Cerrahi Örtü, Önlük ve Örtü Setleri

Reference Report No: MM0403-P005-R01, MM0403-P005-R02
Referans Rapor No

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK II(madde 4 hariç) madde 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen üründen üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, Madde 5'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir. Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır.

This EC certificate is valid till 2024-04-28.
Bu AT Sertifikası 2024-04-28 tarihine kadar geçerlidir.

Issue Date/Yayın Tarihi: 2014-04-30
Revision No./ Revizyon No.: 04 Recertification/ Yeniden Belgelendirme
Revision Date/ Revizyon Tarihi: 2019-04-29

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Tatlısu Mahallesi, Akif İnan Sk. No:1 Umranıye 34774 İSTANBUL / TÜRKİYE

FKMED 34 R 04

Szutest.com.tr



TÜRK STANDARDLARI ENSTİTÜSÜ
TÜRK STANDARDLARINA UYGUNLUK BELGESİ
TURKISH STANDARDS INSTITUTION
CERTIFICATE OF CONFORMITY TO TURKISH STANDARDS

Markanın Tanımı Description of the Mark
TSE  T S E

BELGE NUMARASI REFERENCE NUMBER OF LICENCE	071851-TSE-01/02
BELGENİN İLK VERİLİŞ TARİHİ DATE OF FIRST ISSUE OF LICENCE	15.04.2014
BELGENİN SON GEÇERLİLİK TARİHİ LICENCE VALID UNTIL	26.02.2020
BELGE SAHİBİ KURULUŞUN ADI NAME OF THE LICENCE HOLDER	NURTEKS TEKSTİL VE MEDİKAL SANAYİ DİŞ TİCARET ANONİM ŞİRKETİ
BELGE SAHİBİ KURULUŞUN ADRESİ ADDRESS OF THE LICENCE HOLDER	KÖŞKÜ ÇEŞME MAH. YENİ BAĞDAT CAD. NO:124 GEBZE KOCAELİ/TÜRKİYE
ÜRETİM YERİ ADI NAME OF THE MANUFACTURING PLACE	NURTEKS TEKSTİL VE MEDİKAL SANAYİ DİŞ TİCARET ANONİM ŞİRKETİ
ÜRETİM YERİ ADRESİ ADDRESS OF THE MANUFACTURING PLACE	KÖŞKÜÇEŞME MAHALLESİ YENİ BAĞDAT CADDESİ NO : 124 GEBZE / KOCAELİ KOCAELİ / TÜRKİYE
İPTAL EDİLEN BELGE NUMARASI (Varsa) INDICATION OF SUPERSEDED LICENCE (if any)	071851-TSE-01/01
TEŞCİLLİ TİCARİ MARKA REGISTERED TRADE MARK	BROCHE
İLGİLİ TÜRK STANDARDI RELATED TURKISH STANDARD	TS EN 13795+A1 / 12.06.2013
BELGE KAPSAMI SCOPE OF LICENCE	SURGICAL DRAPES USED AS MEDICAL DEVICES FOR PATIENTS, CLINICAL STAFF AND EQUIPMENT -HIGH PERFORMANCE, SINGLE USE

03.05.2019

On Behalf Of The Head Of Certification Center
AHMET NURSLI KARTAL
MANAGER OF THE TSE ISTANBUL CERTIFICATION
DEPT.

*Bu belge, belgeden alınan ürünün, üretim yerinin Enstitümüzün belirlediği şartları karşıladığını da gösterir.

*Bu belge ile bir suretini tabii edilmemiş, kullanılmaya devam etmekte olan ürünün başka şekilde değiştirilmesini, kopyasını ve satımını yasaklarız.

*TSE İSTANBUL BELGELENDİRME MÜDÜRLÜĞÜ Adres: Çarşıoğlu Tüneli İstasyonu Yana ÇARŞIOĞLUYAZARCIYI - Tel: 2327312731 Faks: 2327231006

*TSE BELGELENDİRME MERKEZİ BAŞKANLIĞI Adres: Necatibey Cad. No:112 06100 Bakanlık/ANKARA - Tel: 0 312 416 94 81 / 416 64 27, Faks: 0 312 416 66 17

e-posta : tsm@tse.org.tr , web : www.tse.org.tr

<https://evrakkontrol.tse.org.tr/BelgeDogrulama.aspx?pspjevrtdk> adresinden belgenin doğruluğunu ve geçerliliğini sorgulayınız.



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CERTIFICATE

This certificate is granted to the organization,

NURTEKS TEKSTİL VE MEDİKAL SANAYİ DİŞ TİCARET ANONİM ŞİRKETİ

Köşklüçşme Mahallesi Yeni Bağdat Caddesi No:124 Gebze / Kocaeli / Türkiye

PRODUCTION OF DISPOSABLE; STERILE SURGICAL GOWNS AND DRAPES, NONSTERILE GOWNS AND DRAPES
SALE OF DISPOSABLE STERILE PRODUCTS; (SURGICAL GLOVES, WOODEN TONGUE DEPRESSOR, SURGICAL
BLADES, FLOWMETER, INFUSION (SERUM) SET, URINE BAG, BLOOD TRANSFUSION SET, BLOOD LANCET)
SALE OF DISPOSABLE NONSTERILE PRODUCTS; (EXAMINATION GLOVES, PE GLOVES, MASK, CAPS, SHOE COVER,
WOODEN TONGUE DEPRESSOR, UNDERPADS, GOWNS AND DRAPES, NON-WOVEN PP FABRICS)

EA 14, 29

according to the scope,

ISO 9001:2015

to certify that Quality Management System in accordance with standard's clauses
is established and being implemented.

First Date of Issue : 03.04.2018
Date of Issue : 02.04.2019
Certificate Period : 3 Years
Reissue Due Date : 02.04.2020
Certificate No : 01.18.7249.112692.D

First Quality Certification
System Certificate Approved
Maltepe / İstanbul / Türkiye



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T: +91 172 8525875 // F: +91 172 4419531
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FQC, Turkey & Critical Location
FQC Uluslar Arası Belgelendirme ve Eğitim Hiz. A.Ş.
Hırametli Cad. Private İş Merkezi No:10 K2 Zemin Kat, Maltepe, Türkiye
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www.fqc.com.tr info@fqc.com.tr

Bu belge, müşterinin FQC'nin kuraları ve sözleşme şartlarına uyduğu sürece geçerlidir. Sertifika geçerlilik durumu FQC'nin internet sitesinden takip edilebilir.
This document shall remain valid as long as the customer obeys FQC rules and terms of the contract. Certificate validity may be checked on FQC website.

CERTIFICATE of Registration



This is to Certify that the
Medical Devices – Quality Management System

of

NURTEKS TEKSTİL VE MEDİKAL SANAYİ DIŞ TİCARET A.Ş.

KÖŞKLÜ ÇEŞME MAH. YENİ BAĞDAT CAD. NO:124 GEBZE / KOCAELİ / TURKEY

has been independently assessed and is compliant
with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

PRODUCTION AND SALES OF DISPOSABLE PRODUCTS; STERILE SURGICAL GOWNS AND DRAPES, NONSTERILE GOWNS AND DRAPES, NONWOVEN FABRICS, NON-KNITTED FABRICS AND APPLICATIONS SALE OF DISPOSABLE STERILE PRODUCTS; (SURGICAL GLOVES, WOODEN TONGUE DEPRESSOR, SURGICAL BLADES, FLOWMETER, INFUSION (SERUM) SET, URINE BAG, BLOOD TRANSFUSION SET, BLOOD LANCET)
SALE OF DISPOSABLE NONSTERILE PRODUCTS; (EXAMINATION GLOVES, PE GLOVES, MASK, CAPS, SHOE COVER, WOODEN TONGUE DEPRESSOR, UNDERPADS, GOWNS AND DRAPES, NON-WOVEN PP FABRICS)
ÜRETİMİ VE SATIŞI YAPILAN TEK KULLANIMLIK ÜRÜNLER; STERİL CERRAHİ ÖNLÜKLER VE ÖRTÜLER, NONSTERİL ÖNLÜKLER VE ÖRTÜLER, DOKUNMAMIŞ KUMAŞLAR, ÖRÜLMEMİŞ KUMAŞLAR VE APLİKASYONLAR
SATIŞI YAPILAN TEK KULLANIMLIK STERİL ÜRÜNLER (CERRAHİ ELDİVENLER, TAHTA DİL BASACAĞI, BİSTURİ UCU, DAMLA AYAR SETİ, SERUM SETİ, İDRAR TORBASI, KAN VERME SETİ, KAN LANSETİ)
SATIŞI YAPILAN TEK KULLANIMLIK NONSTERİL ÜRÜNLER (MUAYENE ELDİVENLERİ, PE ELDİVEN, MASKELER, BONELER, GALOŞLAR, TAHTA DİL BASACAĞI, YATAK KORUYUCU ÖRTÜLER, ÖNLÜKLER VE DOKUNMAMIŞ PP KUMAŞLAR)

Certificate No.: TR51235H

Date of initial registration	06 September 2019
Date of this Certificate	06 September 2019
Surveillance audit on or before	05 September 2020
Recertification Due / Certificate expiry	05 September 2022

This Certificate is property of Staunchly Management & System Services Pvt. Ltd. and remains valid subject to satisfactory surveillance audits.



Director

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Email : info@staunchlyservices.com Web : www.staunchlyservices.com

SMS/F109A/17/REV52

For precise and updated information concerning the present certificate mail to info@staunchlyservices.com

This Certificate is the property of Staunchly Management & System Services Private Limited and shall be returned immediately when demanded

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