TECHNICAL DATA SHEET

SURGICAL DRAPES & SETS
CAPS & COVERALLS &
SHOE COVERS AND GOWNS

1. FABRIC DATASHEET

Nonwoven Material which are used in the production of this special type of fabrics.

Fabric	Raw Material	Color	Weight	Properties
Medical Nonwoven Fabric	PP SS Fabric PP SMS Fabric Triplex Fabric Laminated SMS Fabric	**Medical Blue**	SS 20 gsm (+/- 5gsm) SMS 41 gsm(+/-5gsm) Triplex 55 gsm(+/-2gsm) LaminatedSMS70gsm(+/5gsm)	Antistatic Opaque Soft Touché Hydrophobic Hyghly Breathable Metal Free Impermeable to Microbial Migration OEKO-TEX Certified ISO 9001 Anti-Allergenic

All our fabrics are metal free and do not contain any radioactive elements neither biological products. All our Fabrics are certified by Oeko-tex Standard 100 and manufactured under strict ISO 9001 guidance.

2. FABRIC

2.1. PRODUCTS DESCRIPTION

Fabrics are made to provide high thermal comfort, high flexibility to the operator. They are made of a hydrophobic soft touché nonwoven material with weight min. 20 g/m2 SS and max. 75 g/m2 . Our fabrics have a resistance to liquid penetration of at least 52 cm of H20 according to NWSP 080.6.R0(15) Test Method (Hydrostatic Head). The Fabric used to manufacture the fabric has a thickness of 0.33 mm NWSP 120.1.R0 (15).

Fabrics are folded in a Pasteur Folding way to ensure aseptic application, and keep the sterile and non-sterile area separated during application, tied to internal and external traces with a cardboard box, at the back, near the neck, a Velcro fastening system, elastic and comfortable cuffs with a length of min. 8,00 cm, made of polyester and anti - frayed, seams made of ultrasonic welding technique.

Fabrics have individual size marking in the form of a sticker affixed to the fabrics, allowing identification before unfolding.

1.1. INTENDED USE

Fabrics are intended to be used to protect healthcare professional during surgical procedure and to provide to the user an absolute comfort in the usage. It is mostly intended for the surgeons and practical nurses. With its hydrophobic property the fabrics are design to whist and every liquid from one side to the other and ease the movement of the surgeon during operation. They are mostly use in standard and short duration surgical operation (opthalmic surgery procedure,…)

1.2. CATEGORY

The Fabrics can be classify in the sterile and non-sterile category.

1.3. QUALITY ASSURRANCE

Our Fabrics are manufactured in accordance with the EN ISO 13485 standard. This ensures that we deliver products and services that consistently meet customer requirements, guaranteeing full customer satisfaction.

All our products have a CE label and comply with the requirements of the Medical Device Directive 93/42/EEC.

Our Fabrics are manufactured under Oekotex and ISO 9001 quality guideline.

1.4. SKIN IRRITATION TEST

Test Name Skin Irritation

Guidelines
This study followed the procedures indicated by the following internationally accepted guidelines:

ISO 10993: Biological evaluation of medical devices
ISO 10993-1: Evaluation and testing
ISO 10993-10: Test for irritation and delayed-type hypersensitivity

Testing Facility : Hacettepe University
Faculty of Pharmacy
Department of Pharmacology 06100 ANKARA

OBSERVATION & CALCULATION

Application sites are observed for erythema and oedema at 1st, 24th, 48th, and 72nd hours following the removal of the patches. Only 24th, 48th, and 72nd hours observations are used for calculations. Irritation was scored by using ISO 10993-10, "Scoring system for skin reaction". Irritation grades are presented as mean of two application sites of either test or blank sample. The primary irritation score for each animal is calculated by dividing the sum of all the irritation scores by six (two test/observation sites, three time points). Primary irritation index is calculated by subtracting the sum of primary irritation scores for the blank sample from the sum of primary irritation scores for the test samples and then dividing this difference by the total number of animals (three). According to the calculated primary irritation index values, the results are presented as the appropriate response category which is given below.

TABLE 1: SCORING SYSTEM FOR SKIN REACTION

Reaction	Irritation score
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1 mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Other adverse changes at the skin sites shall be recorded and reported.	

Skin Irritation Scoring Table

RESULT

TABLE 2: MEAN IRRITATION SCORES OF TWO APPLICATION SITES AT 24 th, 48th,72th HOURS

Observation time points (hours)	1st rabbit		2nd rabbit		3rd rabbit	
	Control site	Test site	Control site	Test site	Control site	Test site
24th	0	0	0	0	0	0
48th	0	0	0	0	0	0
72nd	0	0	0	0	0	0
Primary irritation score	**0**	**0**	**0**	**0**	**0**	**0**

Fabric Irritation Test

Primary irritation index: 0

Primary irritation index	Response category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

Response category: Negligible

CONCLUSION

This result indicates that the test sample "**Non woven SMS Kumaş (Endless polypropylene spunbond, thermally bonded SMS)** (Lot1036815)" **does not cause skin irritation.**

Results

1.5. PACKAGING

The Fabrics in its sterilization pouch pack is then double packed in order to reduce all the risks it may encounter during its transportation.

The Fabrics packed in foil-paper packaging is required to be accompanied by a technical card to confirm the required parameters.

The double packed Fabrics are put in standard sized carton which dimensions are: Height= 44cm;Length =40cm and Width=60 cm.

On the outer packaging there are two self-adhesive labels for documentation purposes including: catalogue number, Product SAP Code, LOT Number, expiry date and manufacturer's name.

1.6. OPTION AVAILABLE

- Custom dimensions
- Ultrasonic Welding
- Amount of Towels
- Wrap

2. SHELL LIFE

The fabrics have a Shell life of 3 years.

3. STERILIZATION PROCESS

The well packed Fabrics in their respective boxes with their individual identification labels are then sterilized using Ethylene oxide gas (EO Sterilization). Each sterilization process is strictly controlled and appropriate data (temperature, duration, humidity and gas concentration) are collected by experimented personal. All these data are then saved to our SAP system for traceability. These data can be provided for each sterile product by the bias of their Lot number, reference number and product code.

4. STORAGE CONDITION

Store under ambient temperature and dry condition.

5. REGULATORY

Class IS Rule 1 MDD 93/42/ECC Annex / IX MDD
93/42/ECC ISO 9001
ISO 13485:2016
EN 13795-1
OEKO-TEX STANDARD 100

6. COUNTRY OF ORIGIN

This Fabrics are entirely manufactured in TURKEY by Zeyni Medical Co., Ltd which located in Bursa. Fabrics are fully resistant to traction and elongation.