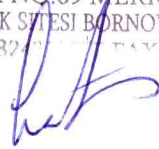


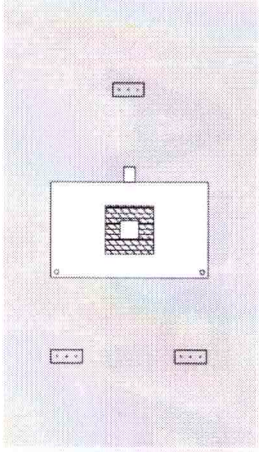
DISPOSED MEDICAL
CESAREAN SECTION PACK
REF NO: D-971
PRODUCT SPECIFICATION

DISPOSED SAĞLIK ÜRÜNLERİ
METİM SANAYİ VE TİCARET İTHALAT İHRACAT LTD. ŞTİ.
748 SOK NO:69 MERİÇ MAHALLESİ
MTK SİTESİ BORNova-İZMİR
TEL:+90232 431 2279 FAX: 002324312279

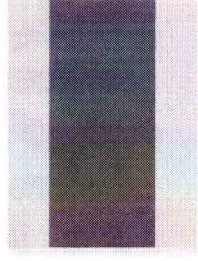


PRODUCT
SPECIFICATION

CESAREAN SECTION PACK



Caesarean Section Drape with Liquid Collection Pouch
200x300 cm



Back Table Cover
150x200 cm



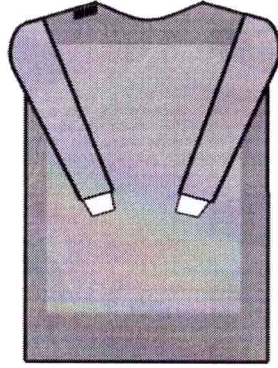
Newborn Drape
75x75 cm



Umbilical Cord Clamp



Towel
40x40 cm



DISPOSED SAĞLIK ÜRÜNLERİ
ETİM SANAYİ VE TİCARET İTHALAT İHRACAT LTD. ŞTİ.
748 SOK NO:69 MERİÇ MAHALLESİ
MTK SİTESİ BORNova-İZMİR
TEL:+902324312279 FAX:+902324312279

A handwritten signature in blue ink.

PRODUCT
SPECIFICATION

CESAREAN SECTION PACK

<u>PRODUCT</u>	<u>quantity</u>
1 Table cover - 150x200 cm	1 pcs
2 Ceserean section drape with collection pouch – 200x300cm"	1 pcs
3 Newborn drape- 75x90 cm	1 pcs
4 Umbelical cord clamp	1 pcs
5 SMS Reinforced surgical gown, size L	2 pcs
6 Hand towel- 40x40 cm	2 pcs
7 Sterilization Wrap 100x100 cm	1 pcs

1) GENERAL INFORMATION

Product Description	CESAREAN SECTION PACK
Reference Number	D-971
PackingQuantity	1 (40x60x50 cm)
Quantityperbox	10
Sterilization	EO (EthyleneOxide)
Certificates	EC Certificate ISO 13485:2016

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 occuring of possible contamination and infection between the patient and the medical team.

ExpirationDate 3years

2) USED MATERIALS

	PRODUCT	FabricType	Micron	g/m2	Colour	Label
1	Ceserean section drape with collection pouch – 200x300cm	DUBLEX		55-60	Medical Blue/green	
2	Table cover - 150x200 cm	PE	80		Blue	
3	Hand Towel	Viscose		70	white	-

3) QUALITY CONTROL RESULTS FOR FABRIC

DUBLEX 55 gr/m2				
EN13795:2011	Test Method	Unit	Requirement (High Performance/Critical Area)	Test Result
Tensile Strength- Dry	EN 29073-3	N	≥ 20	64,38
Tensile Strength-Wet	EN 29073-3	N	Not Required	Not Required
BurstingStrength -Dry	EN ISO 13938-1	kPa	≥ 40	225
BurstingStrength -Wet	EN ISO 13938-1	kPa	Not Required	Not Required
ResistancetoMicrobialPenetration-Dry	EN ISO 11737-1	CFU	≤ 300	47
ResistancetoMicrobialPenetration-Wet	EN ISO 22610	lb	Not Required	Not Required
Cleanliness-Microbial	EN ISO 11737-1	CFU/100cm2	≤ 300	9
Cleanliness-ParticulateMatter	EN ISO 9073-10	IPM	$\leq 3,5$	6
Linting	EN ISO 9073-10	log 10 (lintcount)	$\leq 4,0$	3,6
Resistanceto Liquid Penetration	EN 20811	cm H2O	≥ 10	53

4) PACKAGING

All production

Clean room conditions Medica folding (Window Bag) Sterilization package

Labelling of product

Each unit

- Referans number,
- Lot number,
- Producer description,
- Production date,
- Expiry date,
- Sterilization symbol,
- Single use,
- CE,
- Bar code
- Other customer requests

Storage Instructions

Our disposable products have to be kept without unwrapping the outerpackage. If it will be stored in a warehouse, then it has to be stored with it inner packaging in sterile conditions. In order to keep the product's sterile conditions, it has to be unwrapped from its inner packaging before using it.

Products have to be kept away from humidity, excess airflow and direct sunshine.

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