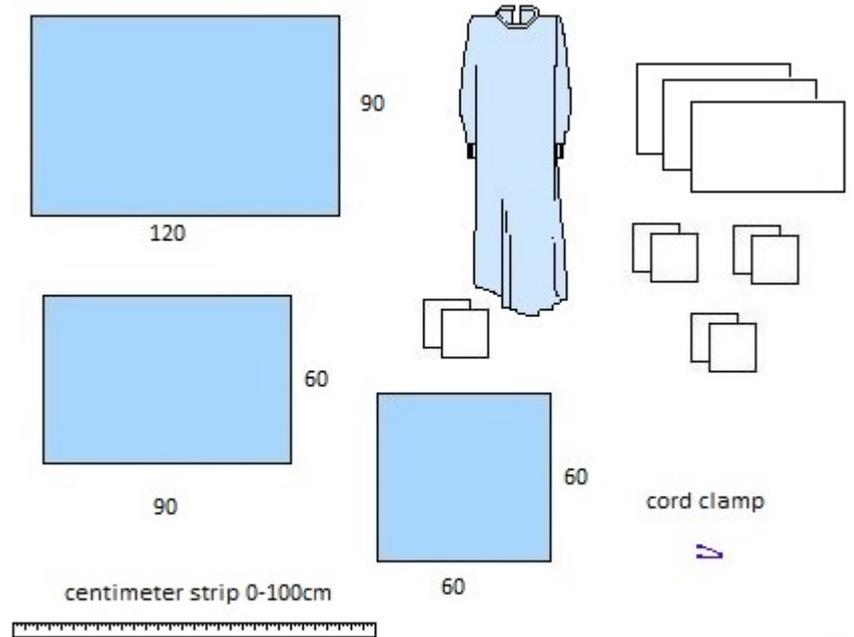


ITEM CODE
SH1732SE

ITEM DESCRIPTION
OBSTETRIC KIT

01 cover drape 90x120cm
01 surgical gown size L Long with towels
01 drape 60x90cm
01 drape 60x60cm
06 towels 34x38cm
03 towel 50x95cm
01 cord clamp
01 centimeter 0-100cm



Betatex S.p.A. products are identified by a lot number to refer to

Packing: Boxes of 6 pieces

Sterilization: Class IIa

Intended use: Indicated for surgery in order to create a barrier against liquids and bacteria and consequently avoid contamination to the patient

QUALITY ASSURANCE

Betatex S.p.A. Assisi adopts a quality system in compliance with the standard UNI EN ISO 9001:2015-UNI EN ISO 13485:2012 certified by DNV GL

The Quality Assurance manual is available on customer's request.

Specific system requirements need to be agreed upon when drawing up the contract

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942.852	30/12/2020	0	30/12/2020	Valeria Busti	Simona Sambuchi	1
Betatex S.p.A. – Viale Europa – 06083 Ospedalichchio di BastiaUmbra (PG) – Italia Tel. +39 (075) 8004872 – Fax +39 (075) 8004972					www.betatex.com info@betatex.com	

ITEM CODE
SH1732SE

ITEM DESCRIPTION
OBSTETRIC KIT

Allowance: ±3%

MATERIALS CHARACTERISTICS

Caratteristiche Characteristics	Valore Value
COVER DRAPE 90X120CM	
ALLERGENICITY	PP+PE: allergens free
LENGTHWISE ELONGATION	PP+PE: (DRY) 55.5%; (WET) 48%(UNI EN 29073-3, EN 13795)
CROSSWISE ELONGATION	PP+PE: (DRY) 47 %; (WET) 46.5 % (UNI EN 29073-3, EN 13795)
ANTISTATICITY	PP+PE: antistatic
ABSORBENCY TIME	PP+PE: 5.4 s (UNI EN ISO 9073-6:2004 par4)
EFFECTIVENESS AGAINST BACTERIAL PENETRATION DRY	PP+PE: 0 UFC (UNI EN ISO 22612, EN 13795)
EFFECTIVENESS AGAINST BACTERIAL PENETRATION WET	PP+PE: IB 6 (UNI EN ISO 22610, EN 13795)
BURSTING STRENGTH	PP+PE: (DRY) 237 kPa; (WET) 240 kPa (UNI EN ISO 13938-1, EN 13795)
ABSORPTION CAPACITY	PP+PE: Absorbent layer about 580%
FLAMMABILITY	PP+PE: Class I (CFR 1610)
CLEANLINESS - MICROBIAL	PP+PE: 0 (CFU/cm2) (UNI EN 11737, EN 13795)
HYDRO HEAD	PP+PE: 144 cm H2O (UNI EN 20811, EN 13795)
COLOR	PP+PE: Uniform color no reflective
DRAPABILITY	PP+PE: draping coefficient 91.1% (UNI EN ISO 9073-9)
WEIGHT	PP+PE: 58 GR/M2
NATURAL LATEX FREE	PP+PE: yes
LINTING	PP+PE: CL 1.8 LOG 10; IPM 1.8 (UNI EN ISO 9073-10) (EN 13795)
AIR PERMEABILITY	PP+PE: no apply
DISPOSAL	PP+PE: Usefull for incinerator
PRESENCE OF TOXIC SUBSTANCES	PP+PE: phtalathes free
LENGTHWISE TENSILE STRENGTH	PP+PE: (DRY) 81.2 N; (WET) 79.2 N (UNI EN 29073-3, EN 13795)
CROSSWISE TENSILE STRENGTH	PP+PE: (DRY) 46.7 N; (WET) 46.5 (UNI EN 29073-3, EN 13795)
GOWN SIZE L LONG	
ANTISTATICITY	GOWN: YES
EFFECTIVENESS AGAINST BACTERIAL PENETRATION DRY	GOWN: 0.3 UFC (EN ISO 22612; EN 13795)
EFFECTIVENESS AGAINST BACTERIAL PENETRATION WET	GOWN: barrier index: 3; (EN ISO 22610; EN 13795)
BURSTING STRENGTH	GOWN: (DRY) 209.1 kPa; (WET) 204.9 kPa IB 6 (EN ISO 22610; EN 13795)
FLAMMABILITY	GOWN: class 1 (CFR 1610)
CLEANLINESS - PART. MATTER	GOWN: 1.0 IPM (ISO 9073-10, EN 13795)
CLEANLINESS - MICROBIAL	GOWN: . 1.8 UFC/100CM2 (EN 11737-1, EN 13795)
HYDRO HEAD	GOWN: 35 cm(UNI EN 20811, EN 13795)

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ITEM CODE	ITEM DESCRIPTION
SH1732SE	OBSTETRIC KIT
COMPOSITION	GOWN: SMMS(Spunbond /Meltblown /Meltblown /Spunbond)
DRAPABILITY	GOWN: 84,9% (UNI EN ISO 9073-9)
WEIGHT	GOWN: 35GR/MQ
NATURAL LATEX FREE	GOWN: YES
PERDITA PARTICELLE (LINTING)	GOWN: 1.1 Log(10) (ISO 9073-10, EN 13795)
AIR PERMEABILITY (PERMEABILITA' ARIA)	GOWN: 0.35 m3/m2/s (ASTM D 737-96)
PERMEABILITY AT STEAM WATER	GOWN: MVTR 2987 g/m2/24h
ALCOHOL REPELLENT (REPEL. ALL'ALCOHOL)	GOWN: 6-8 rating (IST 80.8)
SUPERFICIAL RESISTIVITY Ohms	GOWN: 100 Giga ohm (IST 40.1)
DISPOSAL	GOWN: suitable for incineration
STERILIZATION	GOWN: sterilized by E O
TENSILE STRENGTH - LENGTHWISE	GOWN:(DRY) 76.8N ; (WET) 78.3N (EN 29073-3, EN 13795)
TENSILE STRENGHT -CROSSWISE	GOWN: (DRY) 39.9N ; (WET) 41.2N (EN 29073-3, EN 13795)
TOWEL	
LENGHTWISE ELONGATION	TISSUE: 17%
ABSORBENCY TIME	TISSUE: 3.5 sec
FIRE REACTION CLASS	TISSUE: class 1 (CFR1610)
COMPOSITION	TISSUE: 2 layers of non-woven TNT on each side of polyester mesh (tot: 4 layers)
GRAMMATURA (WEIGHT)	TISSUE: 65.1 gr/m2
NATURAL LATEX FREE	TISSUE: latex free
PRESENCES OF TOXIC SUBSTANCES	TISSUE: phthalates free
DRAPE 60X60CM - 60X90CM	
ALLERGENICITY	PP+PE: allergens free
LENGTHWISE ELONGATION	PP+PE: (DRY) 55.5%; (WET) 48%(UNI EN 29073-3, EN 13795)
CROSSWISE ELONGATION	PP+PE: (DRY) 47 %; (WET) 46.5 % (UNI EN 29073-3, EN 13795)
ANTISTATICITY	PP+PE: antistatic
ABSORBENCY TIME	PP+PE: 5.4 s (UNI EN ISO 9073-6:2004 par4)
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BURSTING STRENGTH	PP+PE: (DRY) 237 kPa; (WET) 240 kPa (UNI EN ISO 13938-1, EN 13795)
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FLAMMABILITY	PP+PE: Class I (CFR 1610)
CLEANLINESS - MICROBIAL	PP+PE: 0 (CFU/cm2) (UNI EN 11737, EN 13795)
HYDRO HEAD	PP+PE: 144 cm H2O (UNI EN 20811, EN 13795)
COLOR	PP+PE: Uniform color no reflective
DRAPABILITY	PP+PE: draping coefficient 91.1% (UNI EN ISO 9073-9)
WEIGHT	PP+PE: 58 GR/M2

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ITEM CODE SH1732SE	ITEM DESCRIPTION OBSTETRIC KIT
NATURAL LATEX FREE	PP+PE: yes
LINTING	PP+PE: CL 1.8 LOG 10; IPM 1.8 (UNI EN ISO 9073-10) (EN 13795)
AIR PERMEABILITY	PP+PE: no apply
DISPOSAL	PP+PE: Usefull for incinerator
PRESENCE OF TOXIC SUBSTANCES	PP+PE: phtalathes free
LENGTHWISE TENSILE STRENGTH	PP+PE: (DRY) 81.2 N; (WET) 79.2 N (UNI EN 29073-3, EN 13795)
CROSSWISE TENSILE STRENGTH	PP+PE: (DRY) 46.7 N; (WET) 46.5 (UNI EN 29073-3, EN 13795)
CITOTOSSICITA' (CYTOTOXICITY)	CLAMP: BIOCOMPATIBLE (ISO 10993)
COMPOSITION	CLAMP: ABS
DIMENSION	CLAMP: 3-1/2" (92 mm) LAMA ACCIAIO 0,2 mm
NATURAL LATEX FREE	CLAMP: YES
TOXICITY	CLAMP: NON TOXIC

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