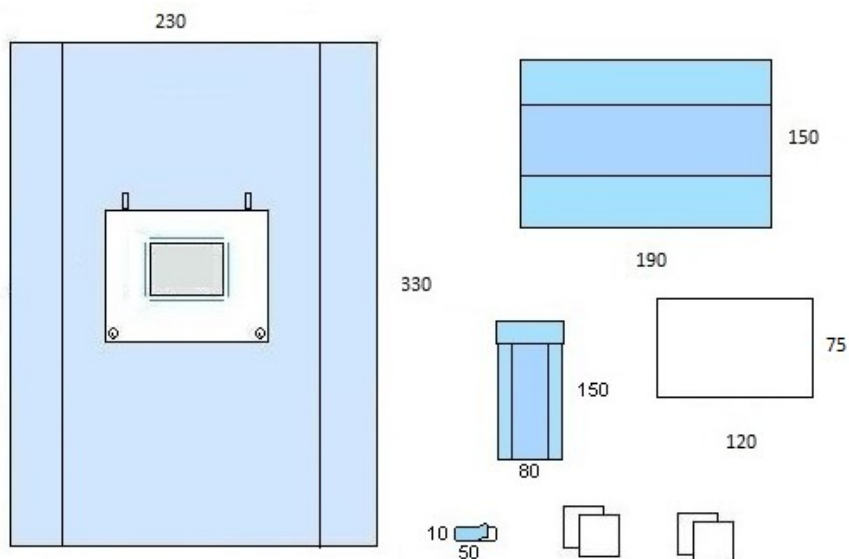


ITEM CODE  
**SH1731SE**

ITEM DESCRIPTION  
**SET FOR CAESAREAN SECTION**

01 caesarean drape 230x330cm in trilaminated material, sidebands in bilaminated material, hole 35x35cm w/incision film and collecting pouch  
01 baby drape 75x120cm  
01 mayo stand cover 80x145cm  
01 OP tape  
04 towels  
01 table cover 150x190cm



**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

Data sheet nr °	Date of issue	Revision nr.	Date of revision	Created by	Product Engineering Manager	Page
942.848	30/12/2020	0	30/12/2020	Valeria Busti	Simona Sambuchi	1
Betatex S.p.A. – Viale Europa – 06083 Ospedalichio di Bastia Umbra (PG) – Italia Tel. +39 (075) 8004872 – Fax +39 (075) 8004972					<a href="http://www.betatex.com">www.betatex.com</a> <a href="mailto:info@betatex.com">info@betatex.com</a>	

ITEM CODE  
**SH1731SE**

ITEM DESCRIPTION  
**SET FOR CAESAREAN SECTION**

**Allowance:** ±3%

## MATERIALS CHARACTERISTICS

Caratteristiche Characteristics	Valore Value
PATIENT DRAPE IN TRILAMINATED 23X330 W/POUCH	
LENGHTWISE STRETCH	TRILAMINATED: (DRY) 55.5 %; (WET) 48 % (UNI EN 29073-3, EN 13795)
CROSSWISE STRETCH	TRILAMINATED: (DRY) 47 %; (WET) 46.5 % (UNI EN 29073-3, EN 13795)
ANTISTATICITY	TRILAMINATED: PE antistatic
EFFECTIVENESS AGAINST BACTERIAL PENETRATION DRY	TRILAMINATED: 0 UFC (UNI EN ISO 22612, EN 13795)
EFFECTIVENESS AGAINST BACTERIAL PENETRATION WET	TRILAMINATED: IB 6 (UNI EN ISO 22610, EN 13795)
BURSTING STRENGTH	TRILAMINATED: (DRY) 237 kPa; (WET) 240 kPa (UNI EN ISO 13938-1, EN 13795)
CAPACITY OF ABSORPTION	TRILAMINATED: absorbing layer about 580%
FIRE REACTION CLASS	TRILAMINATED: Class I (CFR 1610)
CLEANLINESS- MICROBIAL	TRILAMINATED: 0 CFU/100cm <sup>2</sup> (UNI EN 11737, EN 13795)
WATER COLUMN	TRILAMINATED: 144 cm H <sub>2</sub> O (UNI EN 20811, EN 13795)
COLOR	TRILAMINATED: uniform color of non-reflective type
DRAEPABILITY	TRILAMINATED: draping coefficient 88.2% (UNI EN ISO 9073-9)
GRAMMATURA (WEIGHT)	TRILAMINATED: 69gr/m <sup>2</sup> (PP:30gr/m <sup>2</sup> ; PE:25my; PP:12gr/m <sup>2</sup> )
NATURAL LATEX FREE	TRILAMINATED: YES
LINTING	TRILAMINATED: CL 1.8 LOG 10; IPM 1.8 (UNI EN ISO 9073-10, EN 13795)
AIR PERMEABILITY	TRILAMINATED: Not applicable
DISPOSAL	TRILAMINATED: suitable for incineration
PRESENCES OF TOXIC SUBSTANCES	TRILAMINATED: phthalates free
TENSILE STRENGHT LENGHTWISE	TRILAMINATED: (DRY) 81.2 N; (WET) 79.2 N (UNI EN 29073-3, EN 13795)
TENSILE STRENGHT CROSSWISE	TRILAMINATED: (DRY) 46.7 N; (WET) 46.5 N (UNI EN 29073-3, EN 13795)
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/cm <sup>2</sup> ) (UNI EN 11737, EN 13795)

## 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

Data sheet nr °	Date of issue	Revision nr.	Date of revision	Created by	Product Engineering Manager	Page
942.848	30/12/2020	0	30/12/2020	Valeria Busti	Simona Sambuchi	2
Betatex S.p.A. – Viale Europa – 06083 Ospedalicchio di BastiaUmbra (PG) – Italia Tel. +39 (075) 8004872 – Fax +39 (075) 8004972					<a href="http://www.betatex.com">www.betatex.com</a> <a href="mailto:info@betatex.com">info@betatex.com</a>	

ITEM CODE	ITEM DESCRIPTION
<b>SH1731SE</b>	<b>SET FOR CAESAREAN SECTION</b>
HYDRO HEAD	PP+PE: 144 cm H <sub>2</sub> O (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/M <sup>2</sup>
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)
ATOXICITY	VELCRO: phthalates free, does nto contain SVHC
COMPOSITION	VELCRO: NYLON
NATURAL LATEX FREE	VELCRO: yes
ADHESION	INCFILM : to steel: 7.2N/25mm
ALLERGICITY	INCFILM: hypoallergenic
COMPOSITION	INCFILM: support : PE translucent film; asdhesiv: acrylic for medical use; siliconated paper
NATURAL LATEX FREE	INCFILM: YES
LINER RELEASE	INCFILM: 0.09N/25mm
THICKNESS	INCFILM: 0.07mm-0.12mm
STERILIZATION	INCFILM: ETO or Gamma irradiation
PRESENCES OF TOXIC SUBSTANCES	INCFILM: phthalates free
COLLECTING POUCH	
COLOR	FLEX FORM: blue
COMPOSITION	FLEX FORM: Wires coated with polyolefin plastic
NATURAL LATEX FREE	FLEX FORM: latex free
PRESENCES OF TOXIC SUBSTANCES	FLEX FORM: phtalathes free
ANTISTATICITY	POLYETHYLENE.: YES
ATOXICITY	POLYETHYLENE.:YES (DM 21/03/73 and subsequent amendments; EU / 90/128 / EEC Directive)
SELFFLAMMABILITY	POLYETHYLENE.: ca. 340°C
NATURAL LATEX FREE	POLYETHYLENE.: YES
MELTING RANGE	POLYETHYLENE.: 100 - 125 °C
DISPOSAL	POLYETHYLENE.: non-toxic, non-polluting (Presidential Decree No. 915 of 10.09.1982; EEC 94/62)
SPESSORE (THICKNESS)	POLYETHYLENE.: 120 my
COMPOSITION	CONNECTOR: polypropylene
NATURAL LATEX FREE	CONNECTOR: YES
COVER FOR BABY 75X120	

## 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

Data sheet nr °	Date of issue	Revision nr.	Date of revision	Created by	Product Engineering Manager	Page
942.848	30/12/2020	0	30/12/2020	Valeria Busti	Simona Sambuchi	3
Betatex S.p.A. – Viale Europa – 06083 Ospedalicchio di BastiaUmbra (PG) – Italia Tel. +39 (075) 8004872 – Fax +39 (075) 8004972					<a href="http://www.betatex.com">www.betatex.com</a> <a href="mailto:info@betatex.com">info@betatex.com</a>	

ITEM CODE <b>SH1731SE</b>	ITEM DESCRIPTION <b>SET FOR CAESAREAN SECTION</b>
------------------------------	--

LENGHTWISE STRETCH	SPUNLACE: > 24% ( EN 29073-3)
CROSSWISE STRETCH	SPUNLACE: > 60% ( EN 29073-3)
COLOR	SPUNLACE: WHITE
COMPOSITION	SPUNLACE: Viscose; Polyestere
GRAMMATURA (WEIGHT)	SPUNLACE: 60 GR/M2
NATURAL LATEX FREE	SPUNLACE: yes
SPESSORE (THICKNESS)	SPUNLACE: 450 MY (+-30%)
LENGHTWISE TENSILE STRENGHT	SPUNLACE: > 80 N/50mm ( EN 29073-3)
CROSSWISE TENSILE STRENGHT	SPUNLACE: > 80 N/50mm ( EN 29073-3)
MAYO STAND COVER 80X150CM	
ALLERGENICITY	PP+PE: allergens free
LENGHTWISE STRETCH	PP+PE: (DRY) 76,5 %; (WET) 79,5 % (UNI EN 29073-3, EN 13795)
CROSSWISE STRETCH	PP+PE: (DRY) 57,5 %; (WET) 64,5 % (UNI EN 29073-3, EN 13795)
ANTISTATIC	PP+PE: antistatic
ABSORBENCY TIME	PP+PE: 5.4s (UNI EN ISO 9073-6:2004 par 4)
EFFECTIVNESS AGAINST BACTERIAL PENETRATION DRY	PP+PE: 0 UFC (UNI EN ISO 22612, EN 13795)
EFFECTIVNESS AGAINST BACTERIAL PENETRATION WET	PP+PE: IB 6 (UNI EN ISO 22610, EN 13795)
BURSTING STRENGTH	PP+PE: (DRY) 262 kPa; (WET) 256 kPa (UNI EN ISO 13938-1, EN 13795)
ABSORPTION CAPACITY	PP+PE: absorbent layer : about 580%
CLASS REACTION FIRE	PP+PE: Class I (CFR 1610)
CLEANLINESS - MICROBIAL	PP+PE: 0 CFU/cm2 (UNI EN 11737-1, EN 13795)
WATER COLUMN	PP+PE: 178 cm H2O (UNI EN 20811, EN 13795)
COLOR	PP+PE: not reflective uniform color
NATURAL LATEX FREE	PP+PE: YES
LINTING	PP+PE: CL 1,8 LOG 10; IPM 1,8 (UNI EN ISO 9073-10) (EN 13795)
RESISTENCE TO PERFORATION	PP+PE: 14.5 N (UNI EN 863:1997)
DISPOSAL	PP+PE: Useful for incinerator
PRESENCE OF TOXIC SUBSTANCES	PP+PE: phthalates free
LENGHTWISE TENSILE STRENGHT	PP+PE: (DRY) 110 N; (WET) 117 N (UNI EN 29073-3, EN 13795)
CROSSWISE TENSILE STRENGHT	PP+PE: (DRY) 55 N; (WET) 63 N (UNI EN 29073-3, EN 13795)
OP TAPE PP+PE 10X50CM	
LENGTHWISE ELONGATION	PP+PE: (DRY) 58,5 %; (WET) 61,5 % (UNI EN 29073-3, EN 13795)
CROSSWISE ELONGATION	PP+PE: (DRY) 64 %; (WET) 63 % (UNI EN 29073-3, EN 13795)
ABSORBENCE TIME	PP+PE: 5.4 s (UNI EN ISO 9073-6:2004 par.4)
EFFECTIVENESS AGAINST BACTERIAL PENETRATION DRY	PP+PE: <300 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) 233 kPa; (WET) 231 kPa (UNI EN ISO 13938-1, EN 13795)

## 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

Data sheet nr °	Date of issue	Revision nr.	Date of revision	Created by	Product Engineering Manager	Page
942.848	30/12/2020	0	30/12/2020	Valeria Busti	Simona Sambuchi	4
Betatex S.p.A. – Viale Europa – 06083 Ospedaliccchio di BastiaUmbra (PG) – Italia Tel. +39 (075) 8004872 – Fax +39 (075) 8004972					<a href="http://www.betatex.com">www.betatex.com</a> <a href="mailto:info@betatex.com">info@betatex.com</a>	

ITEM CODE	ITEM DESCRIPTION
<b>SH1731SE</b>	<b>SET FOR CAESAREAN SECTION</b>
FIRE REACTION CLASS	PP+PE: Class I (CFR 1610)
CLEANLINESS - MICROBIAL	PP+PE: 0,2 Log10 (CFU/dm <sup>2</sup> ) (UNI EN 11737-1, EN 13795)
HYDRO HEAD	PP+PE: 49,5 cm H <sub>2</sub> O (UNI EN 20811, EN 13795)
WEIGHT	PP+PE: 58 GR/M <sup>2</sup>
NATURAL LATEX FREE	PP+PE: yes
PERDITA PARTICELLE (LINTING)	PP+PE: CL <2,5 LOG 10; IPM 2,2 (UNI EN ISO 9073-10) (EN 13795)
LENGTHWISE TENSILE STRENGTH	PP+PE: (DRY) 90,6 N; (WET) 94,2 N (UNI EN 29073-3, EN 13795)
CROSSWISE TENSILE STRENGTH	PP+PE: (DRY) 47,1 N; (WET) 50,1 N (UNI EN 29073-3, EN 13795)
TOWEL	
LENGTHWISE 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/m <sup>2</sup>
NATURAL LATEX FREE	TISSUE: latex free
PRESENCES OF TOXIC SUBSTANCES	TISSUE: phthalates free
COVER DRAPE IN SPUNBOND+PE 150x190CM	
ALLERGENICITY	PP+PE: allergens free
LENGTHWISE STRETCH	PP+PE: (DRY) 76,5 %; (WET) 79,5 % (UNI EN 29073-3, EN 13795)
CROSSWISE STRETCH	PP+PE: (DRY) 57,5 %; (WET) 64,5 % (UNI EN 29073-3, EN 13795)
ANTISTATIC	PP+PE: antistatic
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) 262 kPa; (WET) 256 kPa (UNI EN ISO 13938-1, EN 13795)
ABSORPTION CAPACITY	PP+PE: absorbent layer : about 580%
CLASS REACTION FIRE	PP+PE: Class I (CFR 1610)
CLEANLINESS - MICROBIAL	PP+PE: 0 CFU/cm <sup>2</sup> (UNI EN 11737-1, EN 13795)
WATER COLUMN	PP+PE: 178 cm H <sub>2</sub> O (UNI EN 20811, EN 13795)
WEIGHT	PP+PE: 79gr/m <sup>2</sup> (PP:30gr/m <sup>2</sup> ; PE:50my)
NATURAL LATEX FREE	PP+PE: YES
LINTING	PP+PE: CL 1,8 LOG 10; IPM 1,8 (UNI EN ISO 9073-10) (EN 13795)
DISPOSAL	PP+PE: Useful for incinerator
LENGTHWISE TENSILE STRENGTH	PP+PE: (DRY) 110 N; (WET) 117 N (UNI EN 29073-3, EN 13795)
CROSSWISE TENSILE STRENGTH	PP+PE: (DRY) 55 N; (WET) 63 N (UNI EN 29073-3, EN 13795)
ALLERGENICITY	PP+PE: allergens free

## 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

Data sheet nr °	Date of issue	Revision nr.	Date of revision	Created by	Product Engineering Manager	Page
942.848	30/12/2020	0	30/12/2020	Valeria Busti	Simona Sambuchi	5
Betatex S.p.A. – Viale Europa – 06083 Ospedalicchio di Bastia Umbra (PG) – Italia Tel. +39 (075) 8004872 – Fax +39 (075) 8004972					<a href="http://www.betatex.com">www.betatex.com</a> <a href="mailto:info@betatex.com">info@betatex.com</a>	