Technical Datasheet

BOP®SI Pouches and reels

Description
Flat pouches and reels for sterilization. Preformed Sterile Barrier System according to ISO 11607-1
Ref Amcor : 01BOP**** – 90BOP**** – 02BOP****
Manufactured product, comprising:

- Top web medical paper 60g/m².
- Bottom web lilac tinted laminate made of 12µm polyester and 38µm polypropylene "shaterless".
- Process indicator for Steam sterilization according to ISO11140-1.
- Does not contain latex
- Absence of TSE / BSE: Complies according to EMEA / 410/01

Sterilization
Steam / Ethylene Oxide
Not suitable for Gamma or Plasma irradiation process

Application
Designed for the packing of a great variety of in-hospital sterilisable products. (linen, trays, dressings, sets, instruments, etc...)
Make sure the packages are correctly sealed to form an effective microbial barrier (EN ISO 11607-2)
Fill the pouches up to 2/3 capacity to allow the good circulation of the sterilizing agent.
Position the packaging plastic to plastic or paper to paper sides together in the steriliser.
Recommended sealing parameters: 170 – 185 °C
"For special material/sealer constellations it might be necessary to vary from the limit values."

At the opening: - Remove the attachment points
- Peel chevron side

Performances
- Excellent peelability.
- Excellent mechanical strength.
- Reduction of noise pollution at the opening
- Microbial Barrier according to EN ISO 11607-1.

Storage
Products should be stored in dry areas away from light and heat.
Temperature range 10°C - 30°C
Relative humidity: 30-60 %
Boxes must not be damaged during handling or storage

Shelf life
5 years from date of manufacturing

Conformity
EN 868-5 and NF EN ISO 11607-1.

Origin
France

CE Mark
Class 1 non sterile

DOMINIQUE DUTSCHER SAS

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Film Web : 12 mµ lilac polyester laminated to a 38 mµ "shaterless" polypropylene.
Paper web : 60 gsm printed paper, tested and validated according to EN 868-3.
Process indicator for Steam sterilization, according to ISO11140-1 (class1).

Paper :

PROPERTIES	UNITS	METHOD	MINI	TYPIC	MAXI
SUBSTANCE	g/m²	ISO 536	57	60	63
BENDTSEN POROSITY	ml/mn	ISO 5636-3	800	1000	1250
AIR PERMEABILITY	µm/(Pa.s)	ISO 5636-3	9,1	11,3	14,2
ROUGHNESS FF	ml/min	ISO 8791-2	250	350	500
ROUGHNESS FT	ml/min	ISO 8791-2	250	350	500
PORE DIAMETER	µm	EN 868-2)		21	35
THICKNESS	µm	ISO 534	74	83	92
TENSILE STRENGTH MD	kNm	ISO 1924-2	4,67	6,3	
TENSILE STRENGTH CD	kN/m	ISO 1924-2	2,33	3,3	
WET TENSILE STRENGTH MD	kN/m	ISO 3781	0,9	2	
WET TENSILE STRENGTHCD	kN/m	ISO 3781	0,45	1	
BURST STRENGTH	kPa	ISO 2758	230	350	
WET BURST	kPa	ISO 3689	70	130	
TEARING STRENGTH MD	Mn	ISO 1974	550	600	
TEARING STRENGTH CD	Mn	ISO 1974	550	650	
COBB TEST (60s)	g/m²	ISO 535		15	20
WATER REPELLENCY	s	EN 868-2	20	35	
FLUORESCENCE	pts/dm²	EN 868-2		0	

Laminate :

PROPERTIES	UNITS	METHODS	VALUES
POLYESTER SUBSTANCE	g/m²	SPS	16 to 17,4
POLYESTER THICKNESS	µm	SPS	12 ± 5 %
ADHESIVE SUBSTANCE	g/m²	SPS	1,65 ± 0,15
POLYPROPLYLENE SUBSTANCE	g/m²	SPS	32,5 to 35,9
POLYPROPYLENE THICKNESS	µm	SPS	36 to 40

Pouches and Reels :

PROPERTIES	UNITS	METHODS	VALUES
SEAL STRENGTH	N/15mm	EN 868-5	≥ 1,5

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