BOP® DI

Self-seal peelable pouches



Sterilization: Compatible with steam sterilization process,ethylene oxide (EO) sterilization process and Formaldehyde sterilization process.
Not suitable for Gamma or Plasma irradiation process.

DESCRIPTION :

Flat self-seal sterilization pouches with steam and EO sterilization process indicators.
Preformed Sterile Barrier System according to EN ISO 11607-1 and EN 868-5.
Product code: S2A***X***
One side 60gsm printed medical paper with an adhesive tape / One side lilac tinted laminate made of 12µm polyester and 38µm polypropylene

- Natural rubber latex free
- TSE / BSE: Compliant with EMEA/410/01

APPLICATION

Designed for the packing of a great variety of in-hospital sterilisable products. (linen, trays, dressings, sets, instruments, etc...)

- 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.
- Bend the top of the pouch as close of the adhesive tape as possible without forming a fold, in order to obtain a sealed closure.
- 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

- It is recommended that the products are kept in the original, closed transport carton and are stored in dry and clean conditions protected from direct sunlight and excessive moisture.
- 5 years from the manufacturing date, provided the above storage conditions are met.

CONFORMITY

EN 868-5 and NF EN ISO 11607-1 & 2

ORIGIN

Made in France



CE MARK

Class I medical device (accessory) according to MDR 2017/745/EU

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TECHNICAL DATA :

Film web : 12µm lilac polyester (PET) laminated to a 38µm “shaterless” polypropylene (PP).
Paper web : 60 gsm printed medical paper, tested and validated according to EN 868-3.
Process indicator for Steam and EO sterilization, according to ISO11140-1 (class1).

PAPER

PROPERTIES	UNITS	METHODS	MIN	TYPIC	MAX
SUBSTANCE	gsm	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 868-2:2017		21	35
THICKNESS	µm	ISO 534	74	83	92
TENSILE STRENGTH MD	kN/m	ISO 1924-2	4.67	6.3	
TENSILE STRENGTH CD	kN/m	ISO 1924-2	2.33	3.3	
WET TENSILE STRENGTHCD	kN/m	ISO 3781	0.9	2	
WET TENSILE STRENGTH MD	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	650	
TEARING STRENGTH CD	mN	ISO 1974	550	650	
COBB TEST (60s)	g/m²	ISO 535		15	20
WATER REPELLENCY	s	EN 868-2:20017	20	35	
FLUORESCENCE	pts/dm²	EN 868-2:20017		0	

LAMINATE

PROPERTIES	UNITS	METHODS	VALUES
POLYESTER SUBSTANCE	gsm	SPS	16 to 17.4
POLYESTER THICKNESS	µm	SPS	12 ± 5 %
ADHESIVE SUBSTANCE	gsm	SPS	1.65 ± 0.15
POLYPROPLYLENE SUBSTANCE	gsm	SPS	32.5 to 35.9
POLYPROPYLENE THICKNESS	µm	SPS	36 to 40

POUCHES

PROPERTIES	UNITS	METHODS	VALUES
SEAL STRENGTH	N/15mm	EN 868-5	≥ 1.5

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