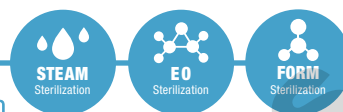


BOP® TI

Gusseted pouches and reels



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

DESCRIPTION :

Gusseted sterilization pouches and reels with steam, EO and Formaldehyde sterilization process indicators.

Preformed Sterile Barrier System according to EN ISO 11607-1 and EN 868-5.

Pouches codes: S2F***X***

Reels codes: G2F***X***

One side 60gsm printed medical paper / One side lilac tinted laminate made of 15µm 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...)

- To close the packaging and create a Sterile Barrier System, the use of a validated heat sealing machine is recommended according to EN ISO 11607-2.
- Make sure to keep a sufficient area to allow the passage of the sterilizing agent (fill to 2/3 max capacity within the packaging)
- Position the packaging plastic to plastic or paper to paper sides together in the sterilizer.
- Recommended sealing parameters: 170 – 195 °C
- Notes: For special material/sealer equipment it might be necessary to vary from the limit values (contact the machine manufacturer and follow their IFU if necessary).
- At the opening for pouches:
 - Remove the attachment points
 - Peel chevron side
- At the opening for reels:
 - Respect the peelability direction printed on the reel to allow best opening performances

PERFORMANCES

- **Excellent peelability**
- **Good mechanical strength**
- **Reduction of noise pollution at the opening**
- **Microbial barrier according to 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

TECHNICAL DATA :

Film web : 15µm lilac polyester (PET) laminated to a 38µm “shatterless” polypropylene (PP).

Paper web : 60 gsm printed paper, tested and validated according to EN 868-3.

Process indicators for Steam, EO and Formaldehyde sterilization, according to ISO 11140-1 (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 STRENGTH MD	kN/m	ISO 3781	0.9	2	
WET TENSILE STRENGTH CD	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 868-2:2017	20	35	
FLUORESCENCE	pts/dm²	EN 868-2:2017		0	

LAMINATE

PROPERTIES	UNITS	METHODS	VALUES
POLYESTER SUBSTANCE	gsm	SPS	21
POLYESTER THICKNESS	µm	SPS	15
ADHESIVE SUBSTANCE	gsm	SPS	1.65 ± 0.15
POLYPROPYLENE SUBSTANCE	gsm	SPS	34.2 +/- 5%
POLYPROPYLENE THICKNESS	µm	SPS	38 +/- 5%

POUCHES

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