# BOP® TI

## Flat 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 :

Flat 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: S2T***X***
Reels codes: G2T***X200
One side 60gsm printed medical paper / 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 sterilizable 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 – 185 °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

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## TECHNICAL DATA :

Film web : 12 µm lilac polyester (PET) laminated to a 38 µm “shaterless” 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 FS | ml/min | ISO 8791-2 | 250 | 350 | 500 |
| ROUGHNESS WS | 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 | 600 | |
| 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 | 16 to 17.4 |
| POLYESTER THICKNESS | µm | SPS | 12 ± 5 % |
| ADHESIVE SUBSTANCE | gsm | SPS | 1.65 ± 0.15 |
| POLYPROPYLENE SUBSTANCE | gsm | 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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