# CLEANTEX®
## pouches

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

## DESCRIPTION :

Flat sterilization pouches.
One side 60gsm non woven - one side lilac tinted printed laminate made of 12µm polyester and 38µm polypropylene.
Preformed Sterile Barrier System according to EN ISO 11607-1.
Pouches codes: SCX***X***

- Natural rubber latex free
- TSE/BSE : compliant to EMEA/410/01

## APPLICATION

**Designed for the packing of bulky medical devices. Used as primary packaging (SBS) and / or secondary packaging (protective packaging).**

- 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 porous to porous 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:
  - Remove the attachment points
  - Peel chevron side

## PERFORMANCES

- **Excellent mechanical strength**
- **Great flexibility and convenience in packaging**
- **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

NF EN ISO 11607-1

## 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 laminated to a 38 µm “shaterless” polypropylene, printed intrafilm.
Porous web : 60 gsm non woven, tested and validated according to EN 868-2.
Process indicator for Steam sterilization according to ISO 11140-1 (class1).

### CLEANTEX®

| PROPERTIES | UNITS | METHODS | MIN | TYPIC | MAX |
|---|---|---|---|---|---|
| SUBSTANCE | gsm | ISO 536 | 57 | 60 | 63 |
| HIGH POROSITY | l/min/1dm² | EN 868-2:1999 | 6 | 18 | |
| THICKNESS (BULKY MATERIAL) | µm | ISO 12625-3 | | 220 | |
| ROUGHNESS FF | ml/min | ISO 8791-2 | 250 | 350 | 500 |
| ROUGHNESS FT | ml/min | ISO 8791-2 | 250 | 350 | 500 |
| TENSILE STRENGTH MD | kN/m | ISO 1924-2 | 1,60 | 2,30 | |
| TENSILE STRENGTH CD | kN/m | ISO 1924-2 | 0,65 | 1,00 | |
| WET TENSILE STRENGTH MD | kN/m | ISO 3781 | 1,2 | 2 | |
| WET TENSILE STRENGTH CD | kN/m | ISO 3781 | 0.5 | 0,8 | |
| BURST STRENGTH | kPa | ISO 2758 | 160 | 230 | |
| WET BURST | kPa | ISO 3689 | 90 | 200 | |
| TEARING STRENGTH MD | mN | ISO 1974 | 750 | 1150 | |
| TEARING STRENGTH CD | mN | ISO 1974 | 1000 | 1700 | |
| STRETCH MD | % | ISO 1924-2 | 5 | 7 | |
| STRETCH CD | % | ISO 1924-2 | 7 | 10 | |
| MASON JAR | min | WSP 80-11 | 75 | 130 | |
| WATER REPELLENCY | s | EN 868-2:20017 | 20 | 30 | |
| 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 |
| POLYPROPYLENE SUBSTANCE | gsm | SPS | 32.5 to 35.9 |
| POLYPROPYLENE THICKNESS | µm | SPS | 36 to 40 |

### POUCH

| PROPERTIES | UNITS | METHODS | VALUES |
|---|---|---|---|
| SEAL STRENGTH | N/15mm | EN 868-5 | ≥3 |
| DIMENSIONS | Mm | SPS | Nominal dimensions ±3 |

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