ULTRA SI
Pouches & reels

Sterilization : Compatible with steam, ethylene oxide (EO), Formaldehyde (Fo), and Vaporized hydrogen peroxide (vH2O2) sterilization processes.
Please revert to your vH2O2 sterilizer manufacturer to confirm the compatibility of ULTRA pouches and reels with their recommended sterilization cycles and processes.

DESCRIPTION :

Flat sterilization pouches/reels.
One side 93 gsm porous material in polyolefin / One side blue tinted laminate made of 12µm polyester (PET) and 38µm polypropylene (PP) "Peel".
Preformed Sterile Barrier System according to EN ISO 11607-1 and EN 868-5.
Pouches codes : SUL***X*** & 98DAV**X**
Reels codes : GUL***X070

- TSE/BSE : compliant to EMEA/410/01

APPLICATION

Designed for the packing of a large variety of single use and reusable medical devices: instrument trays, sets, surgical packs, heavy and bulky devices, complex instruments and every device that requires a specific protection.

- 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)
- Recommended range of sealing temperature :135 -155°C
- Notes: For special material/sealer it might be necessary to vary from the limit values (contact the machine manufacturer and follow their IFU if necessary).
- Reel/Pouch opening:
  - Ultra reels can be opened from both ends.
  -For pouches designed with a chevron: the opening from the chevron side allows facilitate aseptic presentation.

PERFORMANCES

- **Excellent peelability**
- **Excellent 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

SPS MEDICAL
5rue de Montigny • Z.I. • 77120 Coulommiers • France
T +33 (0)164 75 60 00 • F +33 (0)164 75 60 07
https://spsmedical.fr

TECHNICAL DATA :

Film Web: 12 µm blue polyester laminated to a 38 µm polypropylene "peel", printed intrafilm.
Porous Web: 93gsm polyolefin material tested and validated according to EN 868-9.
Steam process indicators according to EN ISO 11140-1 (class1).

POROUS WEB

PROPERTIES	UNITS	METHODS	MIN	TYPIC	MAX
SUBSTANCE	gsm	ISO 536	88	93	98
TENSILE STRENGTH MD	kN/m	EN ISO 1924-2	4.4	5.3	
TENSILE STRENGTH CD	kN/m	EN ISO 1924-2	2.2	3	
TENSILE STRENGTH WET CONDITIONS MD*	kN/m	EN ISO 1924-2	4.4	5.3	
TENSILE STRENGTH WET CONDITIONS CD*	kN/m	EN ISO 1924-2	2.2	3	
BURST STRENGTH	kPa	ISO 2758		580	
TEARING STRENGTH MD	mN	ISO 1974		5670	
TEARING STRENGTH CD	mN	ISO 1974		> 5670	
BENDTSEN POROSITY	ml/mn	ISO 5636-3		2000	
AIR PERMEANCE	µm/(Pa.s)	ISO 5636-3		>23	
PORE SIZE	µm	EN 868-3(app.B)		>31	35
PUNCTURE RESISTANCE	N	ASTM D3763		105	

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	32,49 to 35,91
POLYPROPYLENE THICKNESS	µm	SPS	36,1 to 39,9

POUCHES AND REELS

PROPERTIES	UNITS	METHOD	MIN	TYPIC.	MAX
SEAL STRENGTH	N/15mm	EN 868-5 Annexe D	≥ 1.5	6	-

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