Technical Datasheet

ULTRA SI POUCHES & REELS

Description

Flat sterilization pouches/reels. One side laminate (printed) one side porous material (polyolefin).
Preformed Sterile Barrier System according to EN ISO 11607-1 & 2 and EN 868-5.
Pouches References: : 98ULT**** / Reels References: 99ULT***7O

- One blue laminated web in sandwich printed, made of a 12µm polyester and a 38µmpolypropylene "Peel".
- One 93gsm (average value) polyolefin bottom web.
- Steam process indicators according to ISO11140-1.
- Latex free
- TSE/BSE : Conforming regarding selon EMEA/410/01

Sterilization

Compatible with steam sterilization process, ethylene oxide (EO) sterilization process, and vaporized hydrogen peroxide sterilization process(VH2O2)

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 seal the packaging and create a microbial barrier, the use of a validated heat sealer 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.

Reel/Pouch opening: Ultra web permits opening from both ends, regardless of fiber orientation
For pouches designed with a chevron: The opening from the chevron side can facilitate aseptic presentation.

Performances

- Excellent peelability, no fiber tears, no particles emission.
- Excellent mechanical strength
- Good penetration of the sterilizing agent and facilitates / improves the drying phase.
- High microbial barrier performance (validated before and after sterilization)

Storage

Keep in a dry area, away from direct sunlight or heat source.

Temperature: 10-30°C degrees RH: 30-60%

Outer boxes: avoid physical damage (i.e.: handling and storage), do not use is damaged

Shelf life

5 years from the manufacturing date

Conformity

EN 868-5 et NF EN ISO 11607-1.

Origin

France

CE Mark

Medical Device Class 1 accessory according to MDD 93/42/EEC 1993

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Technical data :

Film Web: 12 mµ blue polyester laminated to a 38 mµ "polypropylene " peel.

Porous Web: Non-woven/polyolefin tested and validated according to EN 868-2 & 3 ; 93gsm (average value) Steam process indicators according to EN ISO 11140-1 (class1)

Porous web:

PROPRIETIES	UNIT	METHOD	TYPIC	MINI	MAXI
SUBSTANCE	g/m^2	ISO 536	93	88	98
TENSILE STRENGTH MD*	kN/m	EN ISO 1924-2	5,3	4,4	
TENSILE STRENGTH CD*	kN/m	EN ISO 1924-2	3	2,2	
TENSILE STRENGTH WET CONDITIONS MD*	kN/m	EN ISO 1924-2	5,3	4,4	
TENSILE STRENGTH WET CONDITIONS CD*	kN/m	EN ISO 1924-2	3	2,2	
BURST STRENGTH	kPa	ISO 2758	580	230	
BURST STRENGTH WET CONDITIONS	kPa		In progress	35	
TEARING STRENGTH MD*	mN	ISO 1974	2000	550	
TEARING STRENGTH CD*	mN	ISO 1974	2000	550	
BENDTSEN POROSITY	ml/mn	ISO 5636-3		>300	
PORE SIZE	µm	EN 868-3(app.B)	31		35
PUNCTURE RESISTANCE	N	ASTM D3763	105		

Laminate:

PROPRIETIES	UNIT	METHOD	TYPIC	MINI	MAXI
POLYESTER SUBSTANCE	g/m^2	SPS	16,7	16	17,4
POLYESTER THICKNESS	µm	SPS	12	11,4	12,6
ADHESIVE SUBSTANCE	g/m^2	SPS	1,65	1,50	1,80
POLYPROPYLENE SUBSTANCE	g/m^2	SPS	33,82	32,12	35,51
POLYPROPYLENE THICKNESS	µm	SPS	38	36,1	39,9

Pre forming:

PROPRIETIES	UNIT	METHOD	TYPIC	MINI	MAXI
SEAL STRENGTH	N/15mm	EN 868-5 Annexe D	6	≥1,5	--

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