

Sterilisation Pouches



PRODUCT INFORMATION	
MATERIAL	Medical grade dialysis paper, double sided tape
COLOUR	Blue (medical composite membrane)
TYPE	Non-sterile, single-use
FEATURES	Triple sealed, thumb-notch open design, compatible with steam & ethylene oxide sterilisation
WEIGHT	60gsm (medical paper), 52 µm (film)
COUNTRY OF ORIGIN	Taiwan
STORAGE	Store in original packaging in a cool, dry and well ventilated area, away from dust, direct sunlight, moisture, x-ray and excessive heat. Ideal temperature: 15-35°C (59-95°F). Relative Humidity: 50-70 RH%.



USAGE GUIDELINES

STACKING MULTIPLE POUCHES

CORRECT METHOD	INCORRECT METHOD
<p>Place pouches film to film and paper to paper.</p> <p>Pouches are stacked back to back with the paper side of the pouches facing each other. This allows a free-flowing in-and-out stream of air and steam between the pouches.</p>	<p>The film of the adjoining pouch covers part of the paper side of the next pouch.</p> <p>This causes a reduced surface area for the penetration of air & steam.</p>

AUTOClave USAGE

Adhere to your Autoclave Manufacturers guidelines when sterilising. Below are recommended guidelines:

Follow your Autoclave instruction manual for the best position for pouch placement.	Pouches should never touch the Autoclave or be overcrowded.

GRADUATED PROCESS INDICATOR EXPOSURE

EO STERILISATION	STEAM STERILISATION
Indicators turn from blue to golden brown when processed 100-120min at 50°C, 60-85% RH, and EO concentration of 600 mg/L.	Indicators turn from pink to cocoa when processed 30min at 121°C. Indicators turn from pink to cocoa when processed 4min at 134°C.
ISO 11135 Sterilisation of health care products - Ethylene oxide-Requirements for the development, validation & routine control of a sterilisation process for medical devices.	ISO 17665 Sterilisation of health care products - Moist heat

QUALITY STANDARDS

AUDIT STANDARDS	Manufactured in an NS EN ISO 13485:2016 facility
TEST STANDARDS	2009-RGC-MDD-0001 - Conforms to Class I device

TEST STANDARDS RESULTS

ITEM	PROPERTIES	UNITS	STANDARDS / METHODS	TYPIC
Medical Paper (A-0101)	Substance	g/m ²	ISO 536	60.0
	Bendtsen Porosity	ml/min	ISO 5636-3	1000
	Air Permeance	µm/Pa.s	ISO 5636-3	11.4
	Bendtsen roughness FS	ml/min	ISO 8791-2	375
	Bendtsen roughness WS		ISO 8791-2	375
	Pore Size	Mm	EN 868-2:2009 Annex E	21.0
	Thickness		ISO 536	83.0
	Tensile strength MD	kN/m	ISO 1924-2	6.4
	Tensile strength CD			3.4
	Wet tensile strength MD	kN/m	ISO 3781	2.1
	Wet tensile strength CD			1.1
	Burst strength	kPa	ISO 2758	350
	Wet burst		ISO 3689	150
	Tearing strength MD	mN	ISO 1974	600
	Tearing strength CD			650
	Cobb test (60s)	g/m ²	ISO 535	15.0
	Water repellency	s	EN 868-2:2009 Annex D	35.0
	Fluorescence	pts/d m ²	EN 868-2:2009 Annex B	0.0
Film (B-BU38)	Thickness	µm	DIn 53370	38.0
	Tensile strength at break MD	N/mm ²	ASTM D-882	41.0
	Tensile strength at break TD			21.0
	Elongation at break MD	%	ASTM D-882	500
	Elongation at break TD			600
Film (B-PET12)	Thickness	µm	ASTM E-252	12 (±5%)
	Tensile strength at break MD	N/mm ²	ASTM D-882	≥ 19.0
	Tensile strength at break TD			
	Elongation at break MD	%	ASTM D-882	≥ 80.0
	Elongation at break TD			

EAGLE ORDERING INFORMATION

CODE	SIZE	PURCHASE UNIT	CARTON DIMENSIONS (LxWxH)	CARTON WEIGHT	CUBIC METRE
412900	134x280mm	1 carton of 2000 pouches (200/box x 10 boxes/ctn)	31 x 30 x 34.5cm	10.1kg	0.03m ³

Certified



Contact us today to receive samples or for more information on this product.

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