

# Mitos klave-it™ Bags

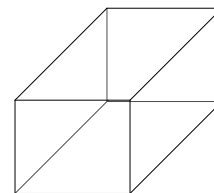
# Teq Speqs

## Film Material

klave-it™ bags are made from a select Kynar® PVDF film that is designed to maintain flexibility, strength and impact resistance after sterilization by autoclave. Because the film is a fluorinated polymer, klave-it bags offer superior chemical resistance and low TOC (total organic carbon) content.



Pillow: 50mL to 200L



3D: 100L to 1000L

## Biocompatibility Testing

Test	Method	Result
Intracutaneous Toxicity	USP Class VI	Pass
Acute Systemic Toxicity	USP Class VI	Pass
Muscular Implantation	USP Class VI	Pass
Hemolysis	ISO 10993-4, 2002	Pass
Physicochemical	USP 28	Pass
Cytotoxicity	MEM Elution, USP 28	Pass

All studies were conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

## Barrier Testing

Test	Method	Value
Oxygen (O <sub>2</sub> ) Transmission	ASTM D-1434	20 cm <sup>3</sup> /m <sup>2</sup> .d.bar
Carbon Dioxide (CO <sub>2</sub> ) Transmission	ASTM D-1434	100 cm <sup>3</sup> /m <sup>2</sup> .d.bar
Water Vapor	ASTM D-1434	2 g/m <sup>2</sup> .d.bar

## Physical Testing

Test	Method	Value
Tensile Strength	ASTM D-638	8000 psi
Elongation at Break	ASTM D-638	800 psi
Modulus at 100% Elongation	ASTM D-638	3300 psi
Tear Strength	ASTM D-1004	1400 Lbf/in
Puncture Resistance	D3763 Dynatub	1.6 Lbf
Operating Temperature	Arkema	-20°F to 285°F

## Mitos Product Testing

Test	Method	Result
Seal Seal Strength	Mitos Air Pressure	Pass, 1L 2 psi/60 sec
Port Seal Strength	Mitos Air Pressure	Pass, 1L 2 psi/60 sec

## Common Chemicals Handled by klave-it Bags

- < 50% Acetic Acid
- Brominated Salts
- Bromine (gaseous)
- Bromine Water
- Bromobenzene
- Chlorinated Salts
- Chlorine
- Chlorobenzene
- Guandine HCl
- Hot Sugars
- Hydrobromic Acid
- Hydrochloric Acid
- Iodine
- Methyl Alcohol
- Methyl Chloroform
- Salicylic Acid
- Salt Water
- Sodium Hypochlorite
- Sulfuric Acid

For a complete list, contact Mitos.

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