

Film Material (animal free)

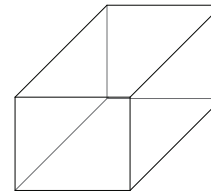
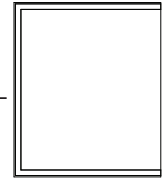
Product Contact Surface

LDPE	Virgin low-density polyethylene for high-purity product contact surface
LLDPE	Linear low-density polyethylene for secondary high-purity contact
EVOH	Ethylene vinyl alcohol for permeation barrier
EVA	Ethylene vinyl acetate for tear and puncture resistance



Flexi Bottle: 1L to 5L

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
Bacterial Endotoxin	LAL	Pass, <0.25 EU/mL extraction media
Gamma Irradiation	AAMI VD _{max}	Pass (with regular audits)

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 ₂) Transmission	ASTM D-3985	0.28 cc/100 in ² /24 hrs
Carbon Dioxide (CO ₂) Transmission	ASTM D-1434	0.58 cc/100 in ² /24 hrs
Moisture Permeability	E-96-80	0.11 g/100 in ² /24 hrs

Physical Testing

Test	Method	Value
Tensile Strength	ASTM D-638	3100 psi (longitudinal & transverse)
Elongation at Break	ASTM D-638	>650 % (longitudinal & transverse)
Modulus at 100% Elongation	ASTM D-638	1100 psi (longitudinal) 1000 psi (transverse)
Tear Strength	ASTM D-1004	550 Lbf/in (longitudinal) 560 Lbf/in (transverse)
Puncture Resistance	FTMS 101B	22.4 Lbf
Operating Temperature	Mitos	-70°C to 70°C

Mitos Product Testing

Test	Parameter	Result
Seam Seal Strength	Mitos Air Pressure	Pass, 1L 5psi/60 sec
Port Seal Strength	Mitos Air Pressure	Pass, 1L 5psi/60 sec

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