



Engineering Excellence in Single-Use Bioprocessing...it's in our DNA

NSUB® BioProcessing Bags (2D & 3D) and all associated tubing sets & assemblies, are manufactured & constructed in ISO 14644 Class VII certified cleanroom facilities, all fluid contact materials using exclusively USP Class VI USFDA & EUP approved components, are supplied sterilised to ISO/TS 13004, typically Gamma Irradiated (s25~40kGy) – ISO 11137 (SAL 10⁻⁶)



General Material Specifications & Approvals:

Fluid Contact Materials:	USP Class VI & EUP
5 Layer BioProcess Co-Extruded Film	LDPE/ULDPE
Manufacturing & Assembly	ISO 14644 Class VII
Sterilisation	ISO 11137-SAL 10 ⁻⁶

Properties & Technical Data:

Haze	7/7%	ASTM D-1003
Clarity	97/97%	ASTM D-1003
Transmittance	93/93%	ASTM D-1003
Tensile Strength	13/14Mpa	ASTM D-882
Elongation Max. %	280/300	ASTM D-882
Elastic Modulus. %	370/350	ASTM D-882
Cold Temp. Resistance	-45/-45!C	ISO 8570
Density	0.9g	ASTM D-792
Water Vapour Transmission Rate (23!C 100% RH)	0.35-0.32(g/(m ² .day))	ASTM F-1249
Carbon Dioxide Permeability Test	< 0.2/< 0.2 (cm ³ /(m ² .day.bar))	ASTM F-2476
Oxygen Permeability Test (23!C 0% RH)	< 0.05/< 0.05(cm ³ /m ² .day.bar))	ASTM D-1385

Regulatory Specifications:

Haemolysis	ISO 10993-4
Cytotoxicity	ISO 10993-5
Implantation test	ISO 10993-6
Acute Systemic Toxicity test	ISO 10993-11
Biological reactivity testing, in vivo, USP Class VI	USP<88>
Irritation and Sensitization tests	ISO 10993-10
Plastic Containers European Pharmacopoeia tests Ch.3.1.5	USP<661>
Bacterial Endotoxins-LAL test	USP<85>