



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:

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|---|--------------------------------------|
| Fluid Contact Materials: | USP Class VI & EUP |
| RENOLIT 9101 (5 Layer BioProcess Co-Extruded Film) | LDPE/ULDPE |
| Manufacturing & Assembly | ISO 14644 Class VII |
| Sterilisation | ISO 11137-SAL 10⁻⁶ |

Properties & Technical Data:

Pre/Post Gamma:

| | | |
|---|--|-------------|
| 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:

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|--|--------------|
| 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> |

NB: The technical information contained in this PDS consists of typical product data and should not be used as a specification & it still remains the responsibility of the downstream user/ customer, or the end user to make sure that articles made of these materials are suited for the intended purpose or use

