PRODUCT DATA SHEET PDS-SU001

SINGLE-USE BioProcess Bags (2D & 3D) & Disposable Assemblies 50ml-3000L

CLARIPURE®
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Engineering Excellence in Single-Use Bioprocessing…it's in our DNA

CLARIPURE® 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
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 (cm3/(m2.day.bar))	ASTM F-2476
Oxygen Permeability Test (23°C 0% RH)	＜0.05/＜0.05(cm^3/m2.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>

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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