Certificate of Compliance

Date	10/01/2024
Product name	VENABIO® 2D SAMPLING BAG
Product Prefix	9003000*
Material	VENA® PE RAD STAB-FILM VENA® PE RAD STAB-PORT
Manufacturing Location	Venair Biotech, Carrer de l'Alguer, 18 – Pol. Ind. Nord - 08226 Terrassa (Barcelona) - Spain

VENA® PE RAD STAB-FILM

Properties*	Unit	Inspection Method	TYPICAL VALUES Prior to / Post Sterilization
Haze	%	7/7	ASTM D-1003
Clarity	%	97/97	ASTM D-1003
Transmittance	%	93/93	ASTM D-1003
Tensile Strenght at break	MPa	14/13	ASTM D-882
Elongation at break, MD/TD	%	370/350	ASTM D-882
Elastic Modulus	MPa	250/270	ASTM D-882
Break at cold temperature	ºC	Below -45/same	ISO 8570
Density	g/cm^3	0.9	ASTM D-792
Water vapor transmission rate**	$gms./m^2/day$ (23° C, 100% RH)	0.35/0.32	ASTM F-1249
O2 permeability**	$cm^3/m^2/day/bar$ (23°C, 0%RH)	<0.05/<0.05	ASTM D-3985
CO2permeability**	$cm^3/m^2/day/bar$ (23°C, 0%RH)	<0.2/<0.2	ASTM F-2476

** **Gauge test film 0.325 mm**
Gamma sterilization dose 25 KGy except **50 KGy

VENA® PE RAD STAB-PORT

Properties	Unit	Inspection Method	TYPICAL VALUES Prior to / Post Sterilization
Elastic Modulus	MPa	175	ASTM D-882
Density	g/cm3	0.92	ASTM D-792
Melt Flow Rate	g/10 min	22(190ºc, 2.16 kg)	ISO 1133
Shore-D hardness	-	45	ISO 868

Process	Quality management system certified ISO 9001:2015, ISO 14001:2015. Produced in ISO7 classified clean room according to ISO14644 in Venair's Spanish manufacturing plant.

Certified information

Regulatory Information	European Pharmacopoeia, Chapter 3.1.5
	USP 85
	USP 87
	USP 88
	USP 232 and USP 233
	USP 661.1
	ISO 10993-4,5,6,10 (Intracutaneous injection test & Delayed type sensitivity test), 11
	US FDA 21 CFR 178.2010
	Extractables Study according to BPOG Guidelines
	Bisphenol A (BPA) Free
	TSE/BSE Free
	REACH Registration, Evaluation, Authorization and Restriction of Chemicals (EC 1907/2006)
	EU Food Packaging legislation (EU) 10/2011
	Packaging and Packaging Waste Directive (Dir. 94/62/EC)
	EMA/EMEA – (CHMP) Guideline on Plastic Immediate Packaging Materials
	ROHS I, ROHS II & ROHS III
	Shelf-Life Statement: 2 years at 23ºC and 50% humidity

Other Testing	100 % Integrity tested with a validated pressure-decay methodology following the guidelines described in ASTM F2095
	Transportation simulation according to ASTM 4169-22
	Internal hang test at maximum nominal volumes for 7 days to ensure integrity during use
	Sterility claim (SAL 10^{-6}) available for irradiated products according to ISO 11137
	Validated Packaging material according to ISO 11167-2 for irradiated products

Approval

Quality Department
Venair Ibérica S.A.U.
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