

Certificate of Compliance

Date	29/09/2023
Product name	VENABIO® SAMPLING BAG & VENABIO® PROCESS 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	°C	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/cm ³	0.92	ASTM D-792
Melt Flow Rate	g/10 min	22(190°C, 2.16 kg)	ISO 1133
Shore-D hardness	-	45	ISO 868

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

Product	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
	Bisphenol A (BPA) Free
	Medical Devices Regulation 2017/745
	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/EMA – (CHMP) Guideline on Plastic Immediate Packaging Materials
	ROHS I, ROHS II & ROHS III
	Shelf-Life Statement: 2 years at 23°C and 50% humidity

Approval

Quality Department

Venair Ibérica S.A.U.

C/Cerdanya 26, Pol. Ind. Nord – 08226 – Terrassa (Barcelona) - Spain

It is the user's responsibility to ensure the suitability and safety of the VENAIR products for all intended uses. All the tests must be conducted in accordance with applicable regulatory requirements to determine the safety and effectiveness for use of the hoses in any particular application. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. Vena, Venair and the Venair logo are trademarks of Venair Ibérica SA.