

Certificate of Compliance

Date	29/09/2023
Product name	VENA® BIO PTFE
Product Prefix	922012*
Material	VENA PTFE TECH 01
Manufacturing Location	Venair Biotech, Carrer de l'Alguer, 18 – Pol. Ind. Nord - 08226 Terrassa (Barcelona) - Spain

Properties	Unit	Inspection Method	Value
Melting Point °C	°C	DIN EN ISO 12086	258 +/- 7
Density	g/cm ³	DIN EN ISO 12086	2.14 ± 0.02
MFI 372-C/5kg	(g/10mi)	DIN EN ISO 1133	2,9 +/- 0,8
Bulk Density	(g/l)	DIN EN ISO 60	1250 +/- 150

Certified information

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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Product	FDA Standard 21 CFR 177.1550
	USP In Vivo <88> Class VI
	TSE/BSE Free
	Animal Derivative Content Free
	Bisphenol A (BPA) Free
	Latex, Phthalates, and Melamine free

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.