



Certificate of Compliance

Date	16/12/2025
Product name	VENA® BIO PTFE
Product Prefix	922012*
Material	VENA PTFE TECH 01, VENA PTFE TECH 02
Company Information	Venair Biotech SLU: C/ Alguer, 26-28 or C/Perpinya 27 (different entrances of the same building) - 08226 Terrassa (Barcelona) - Spain

Table 1. Mechanical parameters of VENA PTFE TECH 01.

Properties	Unit	Inspection Method	Value
Density	g/cm³	ASTM D 4895	2.1725 ± 0.0075
Extrusion pressure	(Mpa)	Internal Method	37.0 ± 5.0
Moisture	%	ASTM D 4895	≤ 0.008
Average Particle Size	(µm)	ASTM D 4895	600 ± 100

Table 2. Mechanical parameters of VENA PTFE TECH 02.

Properties	Unit	Inspection Method	Value
Density	g/cm³	DIN EN ISO 12086	2.165 ± 0.010
Extrusion pressure RR 1:1600	(Mpa)	ASTM D 4895	50.0 ± 8.0
Moisture	%(m)	Internal Method	0.010 ± 0.010
Average Particle Size	(µm)	ISO 13320	400 ± 150

Certified information

Process	Produced under environmentally controlled conditions. Venair Biotech SLU operates under a certified quality management system, compliant with ISO 9001:2015, ISO 14001:2015, and ISO 13485:2016 standards.
Product	FDA CFR 21 177.1550 – Raw material is compliant USP 88 (Class VI) – Raw material is compliant RoHS II Compliant – Restriction of Hazardous Substances SVHC Compliant – Substances of Very High Concern REACH Compliant – Regulation (EC) No. 1907/2006 TSE/BSE Free – Free from Transmissible Spongiform Encephalopathy and Bovine Spongiform Encephalopathy risks ADI Free – No Animal Derived Ingredients BPA Free – Free from Bisphenol A N-nitrosamines Free Latex Free

Approval



VENAIR BIOTECH QUALITY DEPARTMENT
Venair Biotech SLU – C/Perpinya 27 – 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.