

ID Proceso de firma electrónica avanzada: 2ed83fa6-1b01-48ba-b689-4b0ae379216d
Documento firmado electrónicamente a través de InvoSys Soluciones, S.L.U. en 16/12/2025 14:55:20 UTC

Certificate of Compliance

Date	16/12/2025
Product name	VENA® BIO FEP
Product Prefix	922011*
Material	VENA FEP TECH 01, VENA FEP 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 FEP TECH 01.

Properties	Unit	Inspection Method	Value
Melting Point	°C	DIN EN ISO 12086	258 ± 7
Density	g/cm3	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

Table 2. Mechanical parameters of VENA FEP TECH 02.

Properties	Unit	Inspection Method	Value
Melting Point	°C	ASTM D4591 ISO 20568-2	265 ± 15
Density	g/cm3	ASTM D792 ISO 1183	2.145 ± 0.025
Melt Flow Rate	(g/10 min)	ASTM D2116 ISO 20568-2	3.0 ± 0.5
Tensile Strength	Mpa	ASTM D638 ISO 12086-2	≥ 24

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 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 SLU

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.