

## Certificate of Compliance

Emission date	31/01/2024		
Product name	VENA® BIO FLEX		
Product Prefix	9200871*		
Material	VENA TPE FLEX TECH		
Manufacturing Location	Venair Biotech, Carrer de Perpinya, 27 – Pol. Ind. Nord - 08226 Terrassa (Barcelona) - Spain		
Properties	Unit	Inspection Method	Limits
Hardness	Shore A, 10 Sec	ASTM D2240	70±3
Density	g/cm <sup>3</sup>	ASTM D792	0.90±0.02
Tensile Strength	MPa	ASTM D412	>5.0
Tensile Elongation at Break	%	ASTM D412	>300

## Certified Information

Process	Quality management system certified ISO 9001:2015, ISO 14001:2015. Produced in ISO7 classified clean room according to ISO14644.
Product	USP In Vivo <88> Class VI at 121°C
	USP In vitro <87>
	ISO 10993-4, 5, 10, 11 & 23
	FDA Standard 21 CFR 177.2600
	BfR Standard part XV
	Animal Derivative Content Free
	Genetically Modified Organisms (GMO) Free
	Phthalates Free
	PFAS Free
	Melamine Free
	TSE/BSE Free
	Bisphenol A (BPA) Free
	Latex and other allergens Free
	Asbestos Free
	Nitrosamines, N-nitrosatable compounds Free
	Restriction of Hazardous Substances (RoHS)
	REACH Registration, Evaluation, Authorization and Restriction of Chemicals (EC 1907/2006)

## 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.