



Certificate of Compliance

Date	04/11/2025
Product name	VENA® BIO FLEX
Product Prefix	9200871*
Material	VENA TPE FLEX TECH
Manufacturing Location	Venair Biotech SLU: C/ Alguer, 26-28 or C/Perpinya 27 (different entrances of the same building) - 08226 Terrassa (Barcelona) - Spain

Properties	Unit	Inspection Method	Limits
Hardness	Shore A, 10 Sec	ASTM D2240	70±3
Density	g/cm ³	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, ISO 13485:2016. 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


Venair Biotech Quality Department

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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.