

ID Proceso de firma electrónica avanzada: 58e41451-969d-4958-b6dd-749c7a1e1446
Documento firmado electrónicamente a través de Signaturit Solutions, S.L.U. en 15/10/2025 15:11:54 UTC

Certificate of Compliance

Date	15/10/2025
Product name	VENABIO® BRAIDED PLUS
Product Prefix	92008542*
Material	VENA® SILICONE TECH 60
Manufacturing Location	Venair Biotech SLU: C/ Alguer 26-28, Terrassa (08226), Barcelona, Spain

Properties	Unit	Inspection Method	Value
Hardness	Shore A	ISO 868	60 ± 5
Density	g/cm³	ISO 2781	1.16 ± 0.02
Tensile strength	N/mm²	ISO 37	≥7
Elongation at break	%	ISO 37	>300
Tear strength (Method B)	kN/m	ISO 34-1	>20

Certified information

Process	Quality management system certified ISO 9001:2015, ISO 14001:2015 and ISO 13485:2016. Produced in ISO7 classified clean room according to ISO14644 in Venair’s Spanish manufacturing plant.
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Product	USP In Vivo <88> Class VI at 121°C
	USP In vitro <87>
	ISO 10993-4, 5, 10 & 11
	European Pharmacopoeia 3.1.9
	Extractables study according to USP 665
	FDA Standard 21 CFR 177.2600
	BfR Standard part XV
	The requirements of ResAp 2004 (5), according to Reg 1935/2004/EEC
	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.
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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.