

Certificate of Compliance

Date	28/09/2023
Product name	VENA®BIO DOUBLE BRAIDED
Product Prefix	9200855*
Material	VENA® SILICONE TECH 60
Manufacturing Location	Venair Biotech, Carrer de l'Alguer, 18 – Pol. Ind. Nord - 08226 Terrassa (Barcelona) - Spain

Properties	Unit	Inspection Method	Value
Hardness Shore A	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 EMAS. 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

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.