

Certificate of Compliance

Date	18/06/2024
Product name	VENABIO® FLOW 70SHA
Product Prefix	9200853*
Material	VENA® SILICONE TECH 70
Manufacturing Location	Venair Biotech, Carrer Perpinyà, 27 - 08226 Terrassa (Barcelona) - Spain

Properties	Unit	Inspection Method	Value
Hardness	Shore A	ISO 868	70 +/- 5
Tensile strength	N/mm2	ISO 37	≥5
Elongation	%	ISO 37	>300
Tear strength B	kN/m	ISO 34-1	>30
Density	g/cm3	ISO 2781	1,19 +/- 0,03

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	FDA Standard 21 CFR 177.2600
	BfR Standard part XV
	USP In Vivo <88> Class VI at 121°C
	ISO 10993-5 & USP In vitro <87>
	ISO 10993-4, 6 & 10
	European Pharmacopoeia 3.1.9

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.