

Certificate of compliance

Dear customer,

The information of the product described below has been collected to answer the majority of the regulatory compliance requests. However, if there is additional information required that is not provided here, please submit your request to support@vena.bio.

Be advised that this statement also relies on information provided by our suppliers whose materials are used in our manufacturing process, which is provided "as is" and without any re-test from our side. It is the user's responsibility to ensure the suitability and safety of 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 product in any particular application.

Sincerely,

Date	15/01/2020
Product name	VENA [®] BIO PURE ISO7 50SHA
Product prefix	9200851*
Material	VENA [®] SILICONE TECH 50

VENA[®]BIO

BIOTECH TUBING RANGE

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
	The requirements of ResAp 2004 (5), according to Reg 1935/2004/EEC, and Reg 10/2011/EEC
	USP In Vivo <88> Class VI at 121°C
	USP In vitro <87>
	ISO 10993-4, 5, 6 & 10
	European Pharmacopoeia 3.1.9
	ISO 10993-10
	Extractable study
	Animal Derivative Content Free
	Asbestos Free
	Bisphenol A (BPA) Free
	Coalition of Northeastern Governors (CONEG)
	Conflict Minerals (Dodd-Frank Act) Free
	Genetically Modified Organisms (GMO) Free
	Glycerin Free
	Jatropha Plant Free
	Latex, Lactose, Gluten and Allergens Free
	Melamine CAS# 108-78-1
	Metals with Safety Concern (EMEA/CHMP/SWP/4446/2000)
	Phthalates Free
	Plant Origin Free
	REACH Registration, Evaluation, Authorization and Restriction of Chemicals (EC 1907/2006)
Restriction of Hazardous Substances (RoHS)	
Shelf Life and Storage ISO2230	
Slip agent (release agent) Free	
TSE/BSE Free	