

## Certificate of compliance

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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](mailto: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,

<b>Date</b>	07/05/2020
<b>Product name</b>	VENA <sup>®</sup> BIO PURE ISO780ShA
<b>Product prefix</b>	9200857*
<b>Material</b>	VENA <sup>®</sup> SILICONE TECH 80

Mechanical silicone properties	Typical general characteristics	Inspection Method	Value
	Hardness Shore A	ISO 868:2003	80 ± 5
	Density (g/cm <sup>3</sup> )	ISO 2781:2008	1.24 ± 0.02
	Tensile strength (N/mm <sup>2</sup> )	ISO 37:2011	≥7
	Elongation at break (%)	ISO 37:2011	>250
	Tear strength (Method B) (kN/m)	ISO 34-1:2010	>20

<b>Process</b>	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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<b>Product</b>	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 (EMA/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	