

## 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>	08/05/2020
<b>Product name</b>	VENA <sup>®</sup> BIO WELD
<b>Product prefix</b>	9200891*
<b>Material</b>	Vena TPE Tech 52

Mechanical silicone properties	Typical general characteristics	Inspection Method	Value
	Hardness Shore A	ISO 868	52 ± 5
	Density (g/cm <sup>3</sup> )	ISO 1183	0,89 ± 0.02
	Tensile strength (MPa)	ISO 527	>3,8
	Elongation at break (%)	ISO 527	>420
	Tensile Modulus (MPa)	ISO 527	>1,1

<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
	USP <88> USP Biological Test for Plastics, class VI
	EC directive 10/2011/EC
	ISO 10993-4
	ISO 10993-5 & USP In vitro <87>
	Animal Derivative Content Free
	Bisphenol A (BPA) Free
	Phthalates Free
TSE/BSE Free	