

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	08/05/2020
Product name	VENA [®] BIO FEP
Product prefix	922011*
Material	VENA FEP TECH 01

Mechanical silicone properties	Typical general characteristics	Inspection Method	Value
	Melting Point (°C)	DIN EN ISO 12086	258 +/- 7
	Density (g/cm ³)	DIN EN ISO 12086	2.14 ± 0.02
	MFI 372-C/5kg (g/10mi)	DIN EN ISO 1133	2,9 +/- 0,8
	Bulk Density (g/l)	DIN EN ISO 60	1250 +/- 150

Process	Quality management system certified ISO 9001:2015 and ISO 14001:2015.
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Product	FDA Standard 21 CFR 177.1550
	USP In Vivo <88> Class VI
	Animal Derivative Content Free
	Bisphenol A (BPA) Free
	Phthalates Free
	TSE/BSE Free