

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,

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| Date | 15/01/2020 |
| Product name | VENA [®] BIO PURE ISO7 60SHA |
| Product prefix | 9200852* |
| Material | VENA [®] SILICONE TECH 60 |

| Mechanical silicone properties | Typical general characteristics | Inspection Method | Value |
|--------------------------------|---------------------------------------|-------------------|-------------|
| | Hardness Shore A | ISO 868:2003 | 60 ± 5 |
| | Density (g/cm ³) | ISO 2781:2008 | 1.16 ± 0.02 |
| | Tensile strength (N/mm ²) | ISO 37:2011 | ≥7 |
| | Elongation at break (%) | ISO 37:2011 | >300 |
| | Tear strength (Method B) (kN/m) | ISO 34-1:2010 | >20 |

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| 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 |