

May 17th, 2024

Dear customer,

We certify that all our part numbers pertaining to families **VENA® SIL 630, VENA® SIL 640, VENA® SIL 650/V, VENA® SIL 655 and VENA® TECHNOSIL** are in compliance with the requirements of the following food contact regulations:

- FDA-CFR 21, item 177.2600: Rubber articles for contact with food and drugs.
- ResAp 2004 (5), according to Reg 1935/2004/EEC, and Reg 10/2011/EEC.
- BfR Chapter XV: Silicones.
- USP Class VI
- ISO 10993-4, 5, and 10 "Biological evaluation of medical devices".
- European Pharmacopoeia 3.1.9 "Silicone elastomer for closures and tubing".
- 3A Sanitary Standard Procedure 18-03 Class I (material)
- 3A Sanitary Standard 62-02 (fitted hoses)
- Silicone rubber used in accordance with EU Directive 2002/95/ECC for Restriction of the use of hazardous substances (RoHS)

Moreover, we hereby confirm that this product line is manufactured and handled according to the EC regulation No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Sincerely,

Quality Department