

5th March, 2020

Dear customer,

We certify that our reference **VENA® BIO DOUBLE BRAIDED** is 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 standard -121°C standard.
- ISO 10993-4, 5, 6 ad 10 "Biological evaluation of medical devices".
- European Pharmacopoeia 3.1.9 "Silicone elastomer for closures and tubing".
- 3A Sanitary Standard 18-03 Class I (hose)

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

Sincerely,

Quality Department