

**5<sup>th</sup> March, 2020**

Dear customer,

We certify that our reference **VENAFLO<sup>®</sup> HR** inner PFA line is in compliance with the requirements of the following food contact regulations:

- FDA-CFR 21, item 177.1550.
- ResAp 2004 (5), according to Reg 1935/2004/EEC, and Reg 10/2011/EEC.
- USP 87 and USP 88 Class VI standards.
- ISO 10993-5, 10 and 11 "Biological evaluation of medical devices".

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