

Declaration of Compliance „Food and pharmaceutical physiological harmless - BIOCOMPATIBILITY “

We hereby declare that the ePTFE sealing material TEADIT 28LS-LE is in compliance with the following directives, standards and regulations, amendments included:

- **EC Framework Regulation 1935/2004**
- **EU Regulation No. 2023/2006**
- **EU Regulation No 10/2011**
- **U.S. regulations 21 CFR 177.1550**
- **USP 43-NF 38: 2020, <88> / ISO 10993-2: 2006**

Overall migration acc. EU No. 10/2011

Migration tests were performed and have shown that under the test conditions the migration limits were not exceeded.

Specific migration limits (SML) and quantitative maximum (QM) or (QMA) acc. EU No. 10/2011

- Not applicable: Material does not contain substances subject to SML / QM / QMA.
 The following substances are subject to SML and/or QM or QMA limitations and/or specifications. The prescribed values are maintained under the test conditions.

Name of substance	Ref.	SML / QM / QMA

Based on the screening results, including the analytical tolerance, the investigated sample is in compliance with the safety requirements of the Framework Regulation EC 1935/2004 and corresponding EU Regulation 10/2011, including amendments, for the intended use as a high purity ePTFE gasket **up to max. 200 °C**. In addition, the sample is in compliance with the safety requirements according to 21 CFR 170.3 (i).

**TEADIT**[®]

Sealing for a safer and greener tomorrow

BIOCOMPATIBILITY

- USP 43-NF 38: 2020, <88> Biological Reactivity Tests, in vivo - Classification of plastics
- ISO 10993-2: 2006 "Biological evaluation of medical devices – Part 2: Animal welfare requirements"

The sample of the test item, used directly (implantation tests) or extracted at a ratio of 3 cm²/mL and at a temperature of 121 ± 2 °C for 1 hour, met the requirements of a USP Class VI Plastic.

ADI/BSE/TSE

We do not use animal derived ingredients at production. The product is free of BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy).

This declaration of compliance is valid for the product delivered by us and as specified above. The information included in this document is valid for the stated revision versions and dates and/or until this document is superseded.

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