

Declaration of conformity

for commodities in direct contact with foodstuff and application in pharmaceutical plants (physiological safety)

Hereby we declare, that following product – delivered by us –

Designation	Type	Miscellaneous
SISTO diaphragm	EPDM (SE1203) SISTO-AseptiXX	scope of application: SISTO-C

is suitable for application in direct contact with foodstuff and in pharmaceutical plants. The product delivered by us complies with the essential requirements and recommendations, which are defined in the following legal regulations:

a) EU-regulation:

- EC-regulation 1935/2004, including the 07. August 2009 update
- Recommendations of the Federal Institute for Risk Assessment XXI (BfR recommendation: XXI); Commodities made of natural- and synthetic rubber according issue 01. July 2016 following **Category 4**

b) US-regulation: FDA-regulations

- Food and Drug Administration (FDA) according Code of Federal Regulations (CFR), title 21, paragraph 177.2600

c) USP-Guideline:

- USP Guideline 87 "Biological Reactivity Tests, in vitro - Elution Test"
- USP Guideline 88 "Biological Reactivity Tests, in vitro - Classification of plastic" Plastic Class VI - 121°C

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ISO 9001:2015
ISO 14001:2015
ISO 45001:2015

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Used materials

The product produced by us, consists only of materials which are released for Category 4 respectively listed in the “white list”.

Overall migration

The maximum limits for “non fatty foods” of extracted substances, defined in the EU- and FDA-regulations mentioned above are observed under testing conditions and were verified by a corresponding test.

Head of Quality Management

Echternach, den 16.03.2023

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