

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 to issue 01. July 2016 following
Category 4

b) US-Regulation: FDA-Regulations

- Food and Drug Administration (FDA) according to 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 vivo – Classification of plastic" Plastic Class VI – 121 °C

Used materials

The product produced by us, consists only of materials which are released for Category 4 respectively listed in the "whitelist".

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.

Echternach, 17.07.2025

Head of Research and Development

241108; 241319; 241320

Head of Integrated Management



ISO 9001: 2015
ISO 14001: 2015
ISO 45001: 2018

SISTO Armaturen S.A.
18, rue Martin Maas
6468 Echternach / Luxembourg

Tel.: +352 32 50 85-1
Fax: +352 32 89 56
E-Mail: sisto@ksb.com

