

Declaration of conformity

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

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

| Designation | Type | Miscellaneous |
|-----------------|---------------|----------------------------------|
| SISTO diaphragm | EPDM (AA7DKZ) | scope of application: SISTO-C |

is suitable for application in direct contact with foodstuff and in pharmaceutical plant constructions. The product delivered by us complies with the essential requirements, 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, revision 01. April 2017

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 30.10.2017



Management
System
ISO 9001:2008
ISO 14001:2004
OHSAS 18001:2007

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