

# 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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