

# Declaration of conformity

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

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

Designation	Type	Miscellaneous
SISTO diaphragm TFM/EPDM bounded	TFM1700, grade 4025	scope of application: SISTO-C
SISTO diaphragm TFM/EPDM 2-piece	TFM1635, grade TFMX 1630	scope of application: SISTO-C

are suitable for application in direct contact with foodstuff and in pharmaceutical plant constructions. The products delivered by us comply 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
- EU-regulation 10/2011 from 14. January 2011 concerning materials and plastic items, intended to be used in contact with foodstuff. 19. May 2017 update

b) US-regulation: FDA-regulations

- Food and Drug Administration (FDA) according Code of Federal Regulations (CFR), title 21, paragraph 177.1550, revision 01. April 2017

**Used materials**

The product produced by us, consists only of materials which are listed and approved in the corresponding "positive list" respectively "white list"

**Overall migration**

The maximum limits of extracted substances under testing conditions defined in the EU- and US-regulations mentioned above are observed and were verified by corresponding tests.



Head of Quality Management

Echternach, 30. October 2017



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

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