

# 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, 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.

**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 21.10.2022



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

