



### EU- und FDA- Declaration of Compliance for „food and pharmaceutical safety”

We confirm that our

Product:	Ball valve „Series TOPI“
Sealing parts	Ball seat, joint ring, stem sealing
and Sealing materials	a) TFM (PTFE modified) und PTFE (virginal) b) pure graphite

is suitable for use as a material or article for direct contact with food and API and thus in the application in the pharmaceutical plant.

The product complies with the

- EC-Framework Regulation Nr. 1935/2004
- EU-Regulation Nr. 10/2011 and
- US-regulations 21 CFR 177.1550 (The used pure graphite with a purity of 98% or higher meets FDA requirements, as graphite (CAS No. 7782-42-5) is classified as GRAS (Generally Recognized As Safe) in accordance with 21 CFR Part 174.5(d)(1)).

as amended.

#### used materials

The product manufactured by us and the included additives only consist of materials which are listed in the above-mentioned EU positive list and FDA whitelist.

The used auxiliaries in the production are approved by the NSF.

In addition, the maximum permitted amounts of substances are met.

#### Overall migration

In above mentioned guidelines the defined maximum limit of extractables is adhered to under the required test conditions and were detected with a corresponding test.

This is ensured by our sealing- / plastic-suppliers, the declarations of compliance, the traceability and the corresponding QMS-measures.

The prescribed SML and / or QM or QMA values are maintained under the test conditions.

Following substances are included:

PM / Ref.-No.	CAS-No.	Material	SML / SML (T) (mg/kg LM)
25120	116-14-3	Tetrafluorethylene (TFE)	0,05
22937	1623-05-8	Perfluorpropyl-perfluorvinyl ether (PPVE)	0,05

- "Dual-Use-additives": No information available.

- "Not intentionally added substances" - NIAS (Art.19, EU-VO 10/2011):  
No information available

The traceability of the regulation (EC) No. 1935 / 2004 of the product os ensured by our quality management system and corresponding documentation.

Lambsheim, 19.11.2025

Datum

Edwin Günther Chief Executive Officer (CEO)