

# Silicone Weighing Bellows

### Food Contact Compliancy

---

Filcoflex B.V. Netherlands hereby certifies that the following products (1) meet the requirements, and are suitable according to the here under listed (2) regulations and guidelines for the repetitive use in contact with foodstuff materials:

This declaration is based on the results of the migration testing, NIAS study and Compound research all reported and performed by **SGS**.

### Filcoflex Silicone Products to which this Declaration of Compliance applies (1)

- Silicone Weighing Bellows White / Translucent  
801334 / 801335 / 081336 / 801337 / 801338 / 801339  
801340 / 801341 / 801342 / 801344 / 801346 / 801348
  
- Silicone Weighing Bellows Asymmetrical Conical White / Translucent  
801374 / 801375 / 801376 / 801377 / 801380 / 801382 / 801384



### Rules and Regulations to which was tested (2)

#### Regulation (EC) 1935/2004

Materials and Articles intended to come in to contact with food.

Filcoflex B.V. certifies that in the manufacture of our Silicone Bellows (1) our raw material supplier and film manufacturer use monomers & starting substances that comply with relevant requirements of Regulation (EC) 1935/2004)

#### REGULATION (EC) 10/2011

Regulation (EC) 10/2011 does not apply to silicone compounds since no plastics are added in these products.

#### COMMISSION REGULATION (EC) 2023/2006

Good manufacturing practices for items intended to come into contact with food.

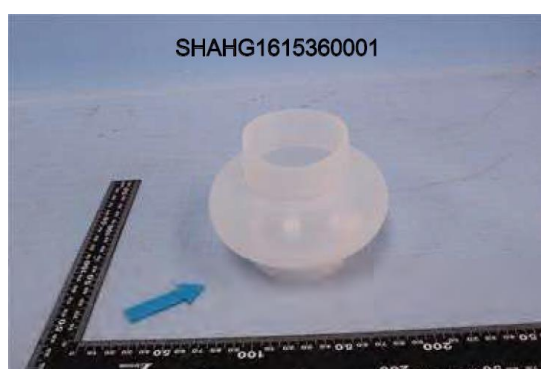
Filcoflex B.V. certifies that in the manufacture of our Silicone Weighing Bellows (1) our raw material supplier and casting manufacturer comply with relevant requirements in Commission Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come in contact with food.

#### FDA

Filcoflex B.V. Netherlands certifies that Silicone Bellows (1) are compliant to FDA 21 CFR 177.2600(e).

As specified by client, to determinate the amount of total extractives from rubber articles intended for Repeated use for compliance with Food and Drug Administration Regulations.

Simulant Used	Time	Temperature	Max Permissible Limit	Result of 001 Total extractives	Comment
Distilled Water	7.00 Hour(s)	Reflux temperature	20mg/inch <sup>2</sup>	<0.5mg/inch <sup>2</sup>	PASS
Distilled Water Succeeding Extraction	2.00 Hour(s)	Reflux temperature	1mg/inch <sup>2</sup>	<0.5mg/inch <sup>2</sup>	PASS
n-Hexane	7.00 Hour(s)	Reflux temperature	175mg/inch <sup>2</sup>	6,8mg/inch <sup>2</sup>	PASS
n-Hexane Exceeding extraction	2.00 Hour(s)	Reflux temperature	4mg/inch <sup>2</sup>	<0.5mg/inch <sup>2</sup>	PASS



### Use of Banned Substance in Silicone Elastomer Weighing Bellows

The following substances are not intentionally added nor suspected to be present in; or used in the production process of any of the Silicone elastomer Weighing Bellows White Translucent (1):

- Lead (Pb)
- Cadmium (Cd)
- Hexavalent chromium (Cr6+)
- Mercury (Hg)
- Phthalates
- Bisphenol A
- Polycyclic aromatic hydrocarbons (PAH)
- Short chain chlorinated paraffins (SCCP)
- Brominated flame retardants, including;
  - o polybrominated biphenyl ether
  - o polybrominated diphenyl ether
  - o octabromobiphenyl ether
  - o pentabromobiphenyl ether
  - o decabromodiphenyl ether

Translucent Silicone elastomer Weighing Bellows (1) and associated production processes are free of any animal derivatives

Translucent Silicone elastomer Weighing Bellows (1) are latex free.

Translucent Silicone elastomer Weighing Bellows (1) do not contain azodicarbonamide blowing agents.

Translucent Silicone elastomer Weighing Bellows (1) do not contain Perfluoro Octane Sulfonates (PFOS).

Translucent Silicone elastomer Weighing Bellows (1) and their processing methods comply with the substance control requirements of the following directives;

(including amendments issued prior to the date of this statement)

- GADSL (formally known as ILRS List 101 and VDA list 232-101)
- EC Directive 76/769/EC
- EC Directive 2011/65/EC (RoHS)
- EC Directive 2002/96/EC (WEEE)
- EC Directive 2002/95/EC
- EC Directive 2000/53/EC (ELV)
- EC Directive 2003/11/EC
- EC Directive 2006/122/EC

Name: **Werner van Loon**  
Position: Managing Director  
Date: 26-10-2021

