

## FOOD CONTACT DECLARATION

Rev. 10/02/2022

This declaration of compliance applies to the following product(s):

- KWO® Universal F Premium
- KWO® Universal R
- KWO® Universal HD
- KWO® CellFlon® Tape
- KWO® CellFlon® R
- KWO® MultiTex® Tape
- KWO® MultiTex® Sheet
- KWO® MultiTex® Ring
- KWO® MultiTex® DK Ring

### Product manufacturer

KWO Dichtungstechnik GmbH  
Am Eschengrund 3  
83135 Schechen  
Germany

### Material Identity

Polytetrafluoroethylene (PTFE)

### Quality System

KWO products are manufactured in a manner that adheres to relevant current Good Manufacturing Practices (cGMP), as defined in a quality system certified to ISO9001.

### Product Application

It is the responsibility of the user to evaluate and determine the suitability of the KWO products for any particular application.

External institutes have performed complex analysis and showed that KWO products comply with the high demands of the food- and pharma industry. Test reports with further details are available on request.

## Declaration of Compliance to Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food:

We hereby declare that the listed articles comply with the regulatory and legislative requirements of **(EC) No. 1935/2004** and the following:

**(EC) No. 2023/2006:** Regulation on Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food.

**(EU) No. 10/2011 (incl. amendments):** Regulation on plastic materials and articles intended to come into contact with food.\*

In the listed articles the following substances with restriction (SML, QM) are used:

Name of substance	PM Ref.	Limits
Tetrafluoroethylene	25120	SML = 0,05 mg/kg

In the listed articles the following dual-use additives are used:

Name of substance	E-number
none	-

### \*Specification of the intended use or limitation:

Type(s) of food intended to come into contact with the material:

- aqueous, acidic, alcoholic and fatty food

Duration and temperature of treatment and storage while in contact with the food:

- repeated use, short term contact (up to 2 hours sterilization at 121 °C)

Ratio of the area of the food contact material to the volume used to determine the compliance of the plastic food contact material or article:

- 6 dm<sup>2</sup> /1000 ml

## Declaration of Compliance to U.S. Food and Drug Administration – FDA

We hereby declare, that for the manufacture of the specified products solely materials are used, which comply, according to the statements of our suppliers/raw material manufacturers, to the requirement of the U. S. Food and Drug Administration (FDA).

- PTFE raw materials comply to the FDA regulations 21 CFR 177.1550, § (a)(1) and (b) Extraction limit values meet 21 CFR 177.1500 § (e)(3)
- for products with adhesive backing, the used adhesive tapes and adhesives comply, according to the statements of our suppliers, to the regulations 21 CFR 175.105 for adhesives.

The used components of the listed products are therefore tested or compliant according FDA.

The declaration is based on the specification of our suppliers.

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