

EC Declaration of Conformity

KE-FDA 25-005

for food contact materials and articles

Manufacturer: KLINGER Kempchen GmbH
Im Waldteich 21
D-46147 Oberhausen

hereby declare that the

Profile gasket type: **Flat gasket and O-ring made of modified PTFE (MPTFE)-Cover (A1 and A10)**

Material: **MPTFE type Inoflon®M295**

may be used in food applications in accordance with the regulations of the U.S. Food and Drug Administration (FDA).

The results of the extractable content test (gravimetric method) on the plastic in question are below the required limits as outlined in the US Code of Federal Regulations (CFR) 21 § 177.1550.

The test was carried out using the following simulants: water, 50% ethanol, n-heptane and ethyl acetate. The duration of the test was two hours, and it was carried out using reflux.

- Requirement extractable fractions (21 CFR 177.1550) max. 0.2 mg/in² - Passed
- Requirement extractable fluorine (21 CFR 177.1550) max. 0.03 mg/in² - Passed

The material used in this instance is in accordance with the FDA's requirements for the test parameters, as specified in US Code of Federal Regulations (CFR) 21 § 177.1550.

This gasket must be specially: ordered, manufactured and cleaned (no stock items)!

The requirements are deemed to be fulfilled if there are no deviations in the order of ordering, production and cleaning with regard to the above-mentioned manufacturer's production process

Should any modification not be agreed upon by us, this declaration shall become invalid.

The gasket or the delivery is labelled as follows:



Oberhausen, 8th May 2025

This certificate is valid without signature.

This translation is based on the actual Version of the German EC Declaration of Conformity „KE-FDA 25-005“. In any case of doubts and possible misinterpretation, whatsoever, only the German version is binding.

KLINGER Kempchen GmbH « Im Waldteich 21 « D-46147 Oberhausen
T.: +49 208 84 82 – 0 « F.: +49 208 84 82 – 285
info@klinger-kempchen.de « www.klinger-kempchen.de
Amtsgericht Duisburg Hdl.-Reg.-Nr. HRB 16971 « Managing Director: Dr.-Ing. Dirk Sunderer