EC Declaration of Conformity

KE-FDA 25-001

for food contact materials and articles

Manufacturer:	KLINGER Kempchen GmbH Im Waldteich 21 D-46147 Oberhausen
hereby declare that the Profile gasket type:	**Moulded part made of modified PTFE (MPTFE)**
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 moulded part 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, 5th 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 25-001“. In any case of doubts and possible misinterpreatation, whatsoever, only the German version is binding.

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