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Reg. No. DK 2325 6118

Declaration of Compliance

Food Contact Materials (FCM), Sealing Parts in PTFE

On behalf of the entire Damstahl group, we hereby declare that all sealing parts of PTFE that have the designation letters "FDA" included in the part description on labels, delivery notes and invoices, supplied by us, are in compliance with:

- **EU 1935/2004** (Materials and articles intended to come into contact with food. Until specific measures for rubber materials is introduced in the EU legislation, article 3 in EU 1935/2004 is considered fulfilled if the material conform to the FDA CFR21 / §177.2600)
- **EU 2023/2006** (Good manufacturing practice, GMP).
- **EU 10/2011** (The determination of the overall migration).
Specific migrations of heavy metals, primary aromatic amines and individual substances with specific migrations limits, was tested by an independent accredited institute. The tests were carried out on representative samples.
According to the regulation (EU) No 10/2011, the total migration was determined by using food simulants and pre-defined testing conditions (time/temperature) that simulate the use in all kinds of foodstuff. The test results did not exceed the legal limits set out in the directive.

This declaration is based on test results from independent labs and/or declarations from the supplier of the material. The following specific substance used to manufacture PTFE has below specific migration limit defined in Annex I of EU regulation No. 10/2011:

CAS No.	Substance name	SML	Result
116-14-3	Tetrafluoroethylene	< 0.05 mg/kg	< 0.05 mg/kg

As well as FDA CFR21 / §177.1550 (per-fluorcarbon resins) incl. overall extraction tests and specific migration tests mentioned in section 3 (1) and (3), (i) (ii) have been passed.

In accordance with FDA CFR21 §177.2600(g), "Good Manufacturing Practice", PTFE and rubber articles intended for contact with food must be thoroughly cleaned prior to food contact.

It remains the customer's own responsibility to determine the suitability of the sealing components for the projected application or application conditions (contact time, contact temperature for the respective types of food stuff). For a quick guide, please consult our guideline "*Rubber and PTFE Recommendations for Food Contact Materials (FCM)*".

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