

DECLARATION OF COMPLIANCE

Issued by: Vaisala Oyj
Vanha Nurmijärventie 21
FI-01670 Vantaa, Finland

Manufacturer: Vaisala Oyj
Vanha Nurmijärventie 21
FI-01670 Vantaa, Finland

We hereby declare that plastic seals used to seal the prism assembly at the sensor tip of K-Patents **PR-23, PR-33-AC and PR-43 -series refractometers**, and the materials used to manufacture these seals meet the relevant requirements laid down in Regulation 1935/2004 of the European Parliament and of the Council, and in the European Commission Regulation 10/2011, valid at the time of writing of this declaration. Manufacturing of these product follows the rules laid down in the European Commission Regulation 2023/2006 (GMP).

Plastic seals are made of PTFE (material Dalcon 001) or Modified PTFE (material Dalcon 086). These materials are derived from tetrafluoroethylene monomer (CAS No. 116-14-3), which is listed in Annex I of the European Commission Regulation 10/2011.

Dalcon 001 and Dalcon 086 materials were tested by an accredited test laboratory for overall migration in accordance with the EU Regulation 10/2011 in the following food simulants:

- Acetic Acid 3%, 4 hours at 100°C
- Ethanol 10%, 4 hours at 100°C
- Rectified Olive Oil, 2 hours at 175°C

Tests confirm that the overall migration released from these materials is below the required limit of 10 mg/dm², and these materials can thus be used in repeated contact with all kinds of foodstuffs up to temperature of 175°C.

Tests were also conducted to confirm these materials comply with the specific migration limits of seven heavy metals (barium, cobalt, copper, iron, lithium, manganese, zinc) specified in the Annex II of the European Commission Regulation 10/2011.

The contact area of the seals with the food material in a process line or vessel is very small, about 12 mm² per one sensor head, and therefore the amount of substances released from the seals into the food material is considered negligible.

Signed for and on behalf of Vaisala Oyj, in Vantaa, on 2nd December 2022



Jari-Pekka Mörsky
Quality Manager, Standards and Approvals