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 Vaisala PR-23, PR-33-AC, PR-43 and PR53 -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 Modified PTFE (material Dalcon 086). This material has been derived from tetrafluoroethylene monomer (CAS No. 116-14-3), which is listed in Annex I of the European Commission Regulation 10/2011.

Dalcon 086 material has been 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 this material is below the required limit of 10 mg/dm^2, and it can thus be used in repeated contact with all kinds of foodstuffs up to temperature of 175˚C.

Tests were also conducted to confirm this material complies 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.

Samples of Dalcon 086 have been tested for compliance to USP Class VI (70˚C) plastic. Testing has been conducted in compliance with the standards published in USP <88> and results show that the material complies with the requirements of the tests.

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 22nd of October 2024

Jari-Pekka Mörsky

Senior Product Compliance Manager

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