

DECLARATION OF CONFORMITY

- For materials made of plastics in contact with foodstuffs -

March 2017

We herewith declare that our hoses / hose assemblies

- type "ELAPHARM"
- type "ELAPHARM OHM"

which come into contact with foods are manufactured with a white or black PTFE inner lining. The lining complies with all applicable current laws and regulations as follows:

- Regulation (EU) No 10/2011/No 2016/1416, No 1282/2011, No 1183/2011 and No 202/2014
- Regulation (EU) No 1935/2004
- Regulation (EU) No 2023/2006
- Consumer Goods Ordinance ("Bedarfsgegenständeverordnung", or "BedGgstV") of 24th June 2013
- German Food and Feed Code ("Lebensmittel- und Futtermittelgesetzbuch", or "LFGB")

The PTFE inner lining is suitable for all reusable food contact conditions with all foods for which testing with food simulants A, B, C, D1, D2 or E is required as per Annex III, Table 2 of the Regulation (EU) No 10/2011/No 2016/1416. The test temperatures of the specified simulants are covered by the valid hose temperature range.

Following the tests with food simulants no after taste or smell could be detected when the lining came in contact with other foodstuffs.

The following materials of the PTFE inner lining are subject to a restriction: tetrafluoroethylene and perfluoropropyl-perfluorovinylether with a maximum value of 0.05 mg/kg LS, 0.0083 mg/dm².

Both global and specific migration were reviewed using food simulants A and B under standard test conditions as per OM 6 and food simulant D2 under standard test conditions as per OM 7, respectively. Maximum allowable values for global migration (10 mg/dm²) and specific migration (0.5 mg/LS, 0.0083 mg/dm²) were not exceeded.

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The ratio of the area that the food was in contact with and the volume used to determine conformity was 200 ml/dm².

Tests were executed by "Hygiene-Institut des Ruhrgebiets", an independent and external test laboratory:

- Test certificates H-245636-14-Bg and test report H-245634-14-Bg for the white PTFE inner lining
- Test certificates H-245648-14-Bg and test report H-245646-14-Bg for the black PTFE inner lining

On top of this, the white as well as black PTFE inner lining are in compliance with FDA 21 CFR 177.1550, CFR 178.3297 and USP Class VI standards, respectively.

Provisions for application and use of ELAPHARM and ELAPHARM OHM are specified in our product data sheet.



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