

CERTIFICATE OF COMPLIANCE

Material: Type of material: polytetrafluoroethylene, 28 LS-LE Sheet No.: 0300012354
(For more information about material identification see BSL Projects No. 133593, 133550.)

Manufacturer: TEADIT Internat. Produktions GmbH, Rosenheimer Str. 10, 6330 Kufstein, Austria

Studies performed: The following studies (BSL Projects No. 133593, 133550-13y265) were carried out in accordance with USP 36 Chapter 87 (2013) "Biological Reactivity Tests, *in vitro* - Elution Test", ISO 10993-1 (2009) "Evaluation and testing within a risk management process", ISO 10993-5 (2009) "Tests for *in vitro* cytotoxicity", ISO 10993-12 (2012) "Sample preparation and reference materials" and ISO 10993-18 (2005) "Chemical characterization of materials".

CYTOTOXICITY TEST

Evaluation of cytotoxic effects of the test material *in vitro* by testing different extract concentrations in cell culture using L929-cells (fibroblast cell line).

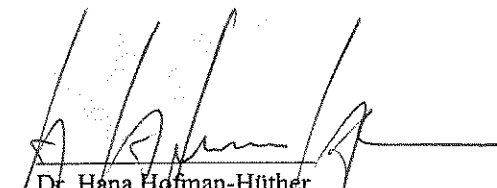
GC/MS FINGERPRINT

Analysis of product-related peaks after extraction of the test items in 0.9% saline solution, PEG 400 and ethanol/0.9% saline solution (1:20) to identify possible volatile or extractable toxic substances as well as to evaluate their toxicological risks.

Results: No relevant leachable substances were released from the test items in cytotoxic concentrations (Reactivity Grade 0). No product-related volatile or semi-volatile substances were detected in the chromatograms of the extracts of the test items. Materials that meet the requirements of the *in vitro* test are not required to undergo *in vivo* testing. Based on this an additional testing according the USP class VI is not necessary.

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