

## Certificate of compliance for USP tests

**Test Item:** TEADIT 30SH  
**Sheet No.:** 24000175A  
**Supplier:** TEADIT Internat. Produktions GmbH,  
Rosenheimer Str. 10, 6330 Kufstein, Austria

**Studies performed:** The following studies were performed in order to determine the biocompatibility of the product TEADIT 30SH (Sheet No.: 24000175A) according to USP <87> and USP <88>:

**CYTOTOXICITY (Eurofins Munich Study No. 162176)**

No leachable substances were released in cytotoxic concentrations from the test item.

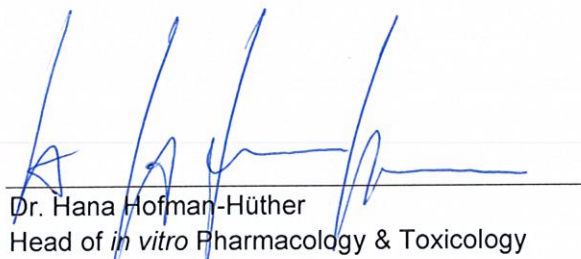
**GC/MS FINGERPRINT (Eurofins Munich Study No. 162177)**

No product-related volatile or semi-volatile substances were detected above or equal to the LOQ in the 0.9% saline solution and in the 5% EtOH in 0.9% saline solution extracts.

**Results:** The sample of the test item extracted at a ratio of 60 cm<sup>2</sup>/20 mL and at a temperature of 121 ± 2 °C for 1 hour (37 ± 1 °C for 24 h for cytotoxicity test), met the requirements of a USP Class VI Plastic. Materials that meet the requirements of the *in vitro* tests 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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Geschäftsführer:

Jure Kapetan, Berthold Hackl

Amtsgericht München, HRB 109 770  
Erfüllung und Gerichtsstand München

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