

ELEPHANT EDELMENTAAL B.V
VERLENGDE LAGEWEG 10
1628 PM HOORN
THE NETHERLANDS
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Lab No. 96T 05420 00

REISSUED REPORT
SUMMARY OF BIOCOMPATIBILITY
APPROPRIATE TO DENTAL APPLICATIONS

Test Article: CARRARA PDF

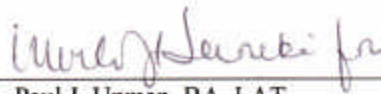
The test article identified above was evaluated for biocompatibility by various biological methods. Testing was conducted to satisfy in part the requirements of dental use materials. Under the conditions of these tests, there was no evidence of toxic or irritant leachables present in the test article.

CYTOTOXICITY (ISO MEM ELUTION): The MEM extract of the test article showed no evidence of causing cell lysis or toxicity to L-929 mouse fibroblast cells.

SENSITIZATION STUDY (MAXIMIZATION METHOD): The saline and cottonseed oil extracts of the test article showed no evidence of causing delayed dermal contact sensitization (allergenicity) in the guinea pig.

MUTAGENICITY SCREEN (AMES TEST): Neither the aqueous or non aqueous extracts of the test article showed any evidence of mutagenic activity following exposure to five different strains of salmonella bacteria, with and without metabolic activation.

Approved By



Paul J. Upman, BA, LAT
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