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REISSUED REPORT  
**SUMMARY OF COMPLIANCE WITH ISO 10993  
BIOLOGICAL EVALUATION OF MEDICAL DEVICES**

Test Article: DG.V08 III – Cera H

Identification No.: Batch 20695

NAMSA Lab No.: 98T-02055-00

The test article identified above was evaluated for biocompatibility by various chemical and biological methods. Testing was conducted to satisfy in part the requirements of dental use materials as well as the International Organization for Standardization (ISO 10993) guidelines. Under the conditions of the tests, there was no evidence of toxic or irritant leachables present in the test article.

**ISO 10993-3: Tests for Genotoxicity**

REVERSE MUTATION ASSAY (AMES TEST): The saline and dimethylsulfoxide extracts of the test article were not considered to be mutagenic to five different Salmonella typhimurium tester strains in the presence or absence of metabolic activation.

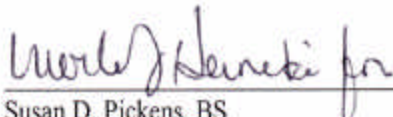
**ISO 10993-5: Tests for Cytotoxicity, in vitro Methods**

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

**ISO 10993-10 Tests for Irritation and Sensitization**

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

Approved By:

  
Susan D. Pickens, BS  
Study Director, Toxicology

July 7, 1998  
Original Date Completed