

CERTIFICATE OF COMPLIANCE

Biocompatibility of the Dental Alloy: "Kera N"

Manufacturer: Eisenbacher Dentalwaren GmbH

Scientific Background and Normative Requirements

"Kera N" is a medical device used as a dental alloy for crowns in the dentistry. The alloy has a long-term contact to human mucous membrane (> 30 d).

Based upon this intended use, and in accordance with DIN EN ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing" - the following biological risks were evaluated: Cytotoxicity, irritation and sensitization.

The tests gave the following results:

Biocompatibility Assessment

Cytotoxicity

The potential of cytotoxicity of the aforementioned test material was investigated in compliance with international GLP regulations, using the elution test method in accordance with DIN EN ISO 10993-5 (mdt report 03z099).

No growth inhibition in all extract-concentrations was observed after an extraction period of 72 h at 37 °C. Therefore, it is concluded that the examined test material caused no cytotoxic reaction.

Irritation Test

The potential of irritation of the test material was investigated in compliance with international GLP regulations, using the intracutaneous reactivity test in accordance with DIN EN ISO 10993-10 (mdt report 07b128).

The test animals exhibited no irritant response. This indicates that the test material has no irritant/corrosive properties.

Sensitization

The potential of sensitization of the test material was investigated in compliance with international GLP regulations, using the maximization test procedure in accordance with DIN EN ISO 10993-10 (mdt report 07b129).

No sensitising effects were observed in the test animals. Therefore, the test material is considered to have no sensitising properties.

Conclusion:

Based upon the aforementioned study results, and considering the provisions of the harmonised standard DIN EN ISO 10993-1 it is concluded that the test material "Kera N" can be evaluated as biocompatible if applied in compliance with its intended use.



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