DECLARATION OF CONFORMITY

Biocompatibility of the Dental Alloy: "Kera-Disc"

Manufacturer: Eisenbacher Dentalwaren GmbH

Scientific Background and Normative Requirements

"Kera-Disc" B 10-39, Art. No. 10041 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 within a Risk Management System" - 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 06z140).

Only the undiluted extract of the test material caused a moderate growth inhibition of 53 % after an extraction period of 72 h at 37 °C. All following extract concentrations showed no growth inhibition.

Considering the test results of the Intracutaneous reactivity test (see below) this moderate growth inhibition is assessed as uncritical for the intended use of the medical device.

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-Disc" B 10-39, Art. No. 10041 can be evaluated as biocompatible if applied in compliance with its intended use.

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-P-974.98.05

mdt medical device testing GmbH
Grenzenstraße 13 • 88416 Ochsenhausen

medical device testing mdt

24.11.2010

Dr. Dieter R. Dannhorn *Date:*
CEO and Scientific Director

Nov. 24, 2010

Michael Ohnmacht, Dipl.-Ing. (FH), Date:
Head of Quality Assurance Unit