Dr. Henning + Co. Dental Engineering

## **Certificate Biocompatibility Test**

Material tested: BegoPal® 300

Dental metal-to-ceramic alloy, ISO 9693 · ISO 22674 · Type 4

Composition/ in % by weight:

Au 6 Pd 75.4 Ag 6.2 In 6.3 Ga 6 Ru

Manufacturer: BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG

Technologiepark Universität  $\cdot$  Wilhelm-Herbst-Str.  $1 \cdot 28359$  Bremen, Germany

**Tests:** We confirm that the following tests for determining the biocompatibility of the

dental alloy were carried out in accordance with the international standards ISO 10993-1992, "Biological evaluation of medical devices" (ISO 10993-1, ISO 10993-5, ISO-DIS 10993-10), DIN-V 13930-1990 "Biological testing of dental materials" and ISO TR 7405-1984 "Biological evaluation of dental materials". The tests were performed according to the OECD code "Good Laboratory Practice" (GLP) by the RCC Institute, Basel, Switzerland and Cytotest Cell Research, Rossdorf, Germany. The tests were coordinated and monitored by Dr. Henning + Co. The specimens were produced by lost wax casting procedure in a commercial dental laboratory according

to the instructions of the manufacturer BEGO.

Cytotoxicity:

The cytotoxic potential of the dental alloy was tested in vitro with L 929 fibroblasts: "Direct cell contact test" ASTM F 813-83.

Test result: BegoPal® 300 had no cytotoxic potential.

Skin irritation and allergic sensitization:

The skin irritation and allergic sensitization were tested with the modified "Open

epicutaneous test" (OET), OECD 406-81.

Test result: BegoPal® 300 did not cause any skin irritation

or allergic sensitization.

Dr. Henning + Co.

Dental Engineering

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Basel, 14. 06. 93