Dr. Henning + Co. **Dental Engineering**

Certificate **Biocompatibility Test**

Material tested:

InLloyd® 100

Crown- and bridge-dental alloy

Composition/ in % by weight:

Au 78.1

Pt 3.9

Ag 15.5

Zn 2.4

Ir 0.1

Manufacturer:

BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG

Technologiepark Universität · Wilhelm-Herbst-Str. 1 · D-28359 Bremen

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/CD/TR 7405-1994 "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., Basel. 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 allow was tested in vitro with L929 fibroblasts. Method: Elution-test with XTT-colouring (ISO 10993-5 and ISO/CD/TR 7405-1994).

Test result:

InLloyd® 100 had no cytotoxic potential.

Skin irritation and allergic sensitization:

The skin irritation and allergic sensitization were tested with the modified epicutaneous-test according to Buehler (ISO-DIS 10993-10, OECD 406-92 and EEC Guidelines 93/21/EEC).

Test result:

InLloyd® 100 did not cause any skin irritation or allergic

sensitization.

Dr. Henning + Co. **Dental Engineering**

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Basel, 20. 12. 94