Dr. Henning + Co.
Dental Engineering

Certificate

Biocompatibility Test

Material tested: **Bio PontoStar®**

Dental alloy for metal-ceramics

Composition / in % by weight:

Au 87	Pt 10.6	Rh 0.2	Zn 1.5	In 0.3	Ta 0.2	Mn 0.2

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, ISO 10993-12), DIN-V 13930-1990 "Biological testing of dental materials", DIN EN 30993-1: 1994 and prEN ISO 7405-1995 "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 Anawa Bioservice, Planegg, 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 alloy was tested in vitro with L929 fibroblasts. Method: Elution-test with XTT-colouring (ISO 10993-5, ISO 10993-12 and prEN ISO 7405-1995).

Test result: **Bio PontoStar® 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 Directive 92/69 EEC).

Test result: **Bio PontoStar® did not cause any skin irritation or allergic sensitization.**

Dr. Henning + Co.
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Basel, 22. 04. 96