

Dr. Henning + Co.
Dental Engineering

Certificate

Biocompatibility Test

Material tested: **PontoLloyd® P**
Dental alloy for metal-ceramics

**Composition/
in % by weight:**

Au 77.5 Pt 9.9 Pd 8.9 Ag 1.0 Cu 0.3 Sn 0.5 In 1.4 Ir 0.1 Fe 0.4

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

Test result: **PontoLloyd® P 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: **PontoLloyd® P did not cause any skin irritation or allergic sensitization.**

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CH-4051 Basel Steinenvorstadt 13



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