

Certificate Biocompatibility Test

Material tested : **PONTOSTAR® G**
Dental metal-to-ceramic alloy

Composition/
in % by mass :

Au 85,6	Pt 11,4	In 2,3	Fe 0,5	Rh 0,2
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Manufacturer: **BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co.**
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 13 930-1990 "Biological testing of dental materials" and ISO TR 7405-1984 "Biological evaluation of dental materials". The tests were performed according to the OECD "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 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: "Direct cell contact test", ASTM F 813-83.

Test result: **PontoStar® G had no cytotoxic potential.**

Skin irritation and allergic sensitisation:

The skin irritation and allergic sensitisation were tested with the "modified Open epicutaneous test" (OET), OECD 406-81.

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

Dr. Henning + Co.
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