

Certificate

Biocompatibility Test

**Material tested /
in % by weight:**

Wiron® 99
Dental metal-to-ceramic alloy

Composition:

Ni 65	Cr 22.5	Mo 9.5	Nb 1	Si 1	Fe 0.5	Ce 0.5
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Manufacturer:

BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co.
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-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 a commercial dental laboratory according to the instructions of the manufacturer BEGO by lost wax casting procedure.

Cytotoxicity

The cytotoxic potential of the dental alloy was tested in vitro with L929 fibroblasts: "Direct cell contact test" ASTM F 813-83 and "Agar diffusion test", ASTM F 895-84 with extract from the specimens.

Test result:

Wiron® 99 had no cytotoxic potential.

Irritation and allergic sensitization:

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

Test result:

Wiron® 99 did not cause any skin irritation or allergic sensitization.

Dr. Henning + Co.

Dental Engineering

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Basel, 19. 03. 93

