

Certificate

Biocompatibility Test

Material tested

WIRONIUM® plus

Dental alloy for co/cr casting

Composition/
in % by mass:

Co 62	Cr 29.53	Mo 5	Si 1	Mn 0.5	Fe 0.5	Ta 0.5	N 0.3	C 0.17
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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, DIN EN 3099-1, 5 "Biological evaluation of medical devices" (ISO 10993-1, ISO 10993-5, ISO-DIS 10993-10), ISO 10993-12 and pr EN ISO 7405-95 "Präklinische Beurteilung der Gewebeträgbarkeit von Medizinprodukten in der Zahnmedizin - Prüfverfahren". 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 an independent 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 ISO 10993-5-92, pr EN ISO 7405-95 (5.2.1.c).

Test result:

WIRONIUM® plus had no cytotoxic potential.

Irritation and allergic sensitization

The skin irritation and allergic sensitization were tested with the modified epicutaneous test according to Buehler (ISO 10993-10, pr EN ISO 7405-95 (5.2.2.e), OECD 406-92 and EEC Guidelines 93/21/EEC).

Test result:

WIRONIUM® plus did not cause any skin irritation or allergic sensitization.

Dr. Henning + Co.

Dental Engineering

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