

CERTIFICATE

Biocompatibility Test

Material tested:

AGC[®] SPEZIALLEGIERUNG

Dental metal-ceramic alloy

Composition:

Au	Pt	Rh	Zn	In	Fe
85.8	11.5	0.5	1.5	0.3	0.4

in % by mass

Manufacturer:

Wieland Edelmetalle GmbH & Co.
Schwenninger Str. 13 · D-75179 Pforzheim

Tests:

We confirm that the following tests for determining the biocompatibility of the dental alloy were carried out in accordance with the international standards EN ISO 10993

"Biological evaluation of medical devices" (EN ISO 10993-1, EN ISO 10993-2, EN ISO 10993-5, EN ISO 10993-10, EN ISO 10993-12) and EN ISO 7405:1997,

"Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials."

The tests were performed according to the OECD directive "Good Laboratory Practice" (GLP) by the Institute BSL Bioservice Scientific Laboratories.

The tests were coordinated and monitored by Dr. Henning + Co.

The specimens were produced by lost wax casting procedure by a commercial dental laboratory, according to the instructions of the manufacturer Wieland Edelmetalle.

Cytotoxicity:

The cytotoxic potential of the dental alloy was tested in vitro with L-929 fibroblasts.

Method: "Test on extracts", XTT staining, EN ISO 10993-5:1999, EN ISO 10993-12:1996, and EN ISO 7405:1997, (5.4.a)3)).

Test result:

AGC[®] SPEZIALLEGIERUNG had no cytotoxic potential

Allergic sensitization:

The allergic sensitization was tested with the Maximisation-Test (Magnusson-Kligman), EN ISO 10993-10:1995 (6.3) "Tests for irritation and sensitization", EN ISO 7405:1997 (5.4.b)5)), OECD 406-92 and Directive 92/69 EEC, B.6.

Test result:

AGC[®] SPEZIALLEGIERUNG did not cause allergic sensitization

Dr. Henning + Co., Dental Engineering
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