

CERTIFICATE

Biocompatibility Test

Material tested

EURO 45

Dental metal-ceramic alloy

Composition

Au	Pd	Ru	Ag	In	Ga	Sn
40.0	39.4	0.1	10.0	8.8	1.4	0.3

in % by mass

Manufacturer

Wieland Dental + Technik GmbH & Co. KG
Schwenninger Straße 13 · D-75179 Pforzheim · Germany

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

"Biological evaluation of medical devices" (ISO 10993-1, ISO 10993-5, ISO/DIS 10993-10, ISO 10993-12), EN 30993-1, -5, and prEN ISO 7405:1995, "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 Institutes RCC, Switzerland, and ANAWA Bioservice, Germany.

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.

Cytotoxicity

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

Method: "Test on extracts", XTT staining (ISO 10993-5, EN 30993-5, and prEN ISO 7405:1995 (5.2.1.c)).

Test result:

EURO 45 had no cytotoxic potential

Skin irritation and allergic sensitization

Skin irritation and the capacity of allergic sensitization were tested with the modified epicutaneous test according to Buehler (ISO/DIS 10993-10 (6.3)

"Tests for irritation and sensitization", prEN ISO 7405:1995 (5.2.2.e), OECD 406-92, and Directive 92/69/EEC, B.6.).

Test result:

EURO 45 did not cause skin irritation or allergic sensitization

Dr. Henning + Co., Dental Engineering

Steinenvorstadt 13 · CH - 4051 Basel



Basle, May 31, 1996