

CERTIFICATE

Biocompatibility Test

Material tested

BioPorta G

Dental metal-ceramic alloy

Composition

Au	Pt	Rh	Zn	In	Fe	W
85.5	11.5	0.5	1.5	0.3	0.2	0.5

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 10993-10, ISO 10993-12), DIN EN 30993-1, and prEN ISO 7405:1995 "Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods".

The tests were performed according to the OECD code "Good Laboratory Practice" (GLP) by the Institutes RCC, Switzerland, and BSL Bioservice, Germany. The tests were coordinated and monitored by Dr. Henning + Co.

The specimens were produced by lost wax casting procedure in 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, DIN EN 30993-5, ISO 10993-12, and prEN ISO 7405:1995 (5.2.1.c)).

Test result:

BioPorta G 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 10993-10 (6.3), prEN ISO 7405:1995 (5.2.2.e), OECD 406-92, and Directive 92/69/EEC, B.6.).

Test result:

BioPorta G did not cause skin irritation or allergic sensitization

Dr. Henning + Co., Dental Engineering
Steinenvorstadt 13 · CH - 4051 Basel



Basle, January 08, 1997