

CERTIFICATE

Biocompatibility Test

Material tested

Porta Maximum

Dental metal-ceramic alloy for high expanding ceramics

Composition

Au	Pt	Pd	Rh	Ag	In	Zn
70.0	10.0	2.5	0.5	10.0	5.0	2.0

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), and DIN V 13930:1990 "Biologische Prüfung von Dentalwerkstoffen". The tests were performed according to the OECD directive "Good Laboratory Practice" (GLP) by the Institutes RCC, Switzerland, and CCR, 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: "Direct cell contact assay" (ASTM F 813-83:1988).

Test result:

Porta Maximum 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 (OECD 406-92, ISO/DIS 10993-10, and Directive 92/69/EEC, B.6.).

Test result:

Porta Maximum did not cause skin irritation or allergic sensitization

Dr. Henning + Co., Dental Engineering
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Basle, February 23, 1994