

# CERTIFICATE

## Biocompatibility Test

Material tested

### Porta SMK 82

Dental metal-ceramic alloy

#### Composition

Au	Pd	Pt	Ru	In	Ga
57.5	31.4	1.5	0.1	8.0	1.5

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 10993-1 "Biological evaluation of medical devices", and DIN V 13930:1990 "Biologische Prüfungen 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 SMK 82 had no cytotoxic potential**

#### Skin irritation and allergic sensitization

Skin irritation and the capacity of allergic sensitization were tested by a modified version of the "Open Epicutaneous Test" (OET) (OECD 406-81, and Directive 84/449/EEC, B.6.).

Test result:

**Porta SMK 82 did not cause skin irritation  
or allergic sensitization**

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



Basle, May 20, 1992