

# CERTIFICATE

## Biocompatibility Test

### Material tested

## BioPortadur

Dental gold casting alloy

### Composition

Au	Pt	Rh	Zn	In
85.3	10.0	0.7	3.0	1.0

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, ISO 10993-12), EN 30993-1, -5, and prEN ISO 7405:1995 "Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods".

The tests were performed according to OECD code "Good Laboratory Practice" (GLP) by the Institutes RCC, Switzerland, and ANAWA Bioservice, Germany.

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

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

### 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:

***BioPortadur 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), prEN ISO 7405:1995 (5.2.2.e), OECD 406-92, and Directive 92/69/EEC, B.6.).

Test result:

***BioPortadur did not cause skin irritation or allergic sensitization***

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



Basle, August 30, 1996