

CERTIFICATE

Biocompatibility Test

Material tested

Portadur P2

Dental gold casting alloy

Composition

Au	Pt	Pd	Ir	Ag	Cu	Zn
71.0	2.5	1.5	0.1	12.2	12.2	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 Draft 10993:1991

"Biological testing of medical and dental materials and 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:

Portadur P2 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:

**Portadur P2 did not cause skin irritation
or allergic sensitization**

Dr. Henning + Co., Dental Engineering

Steinenvorstadt 13 · CH - 4051 Basel



Basle, January 22, 1992