

CERTIFICATE

Biocompatibility Test

Material tested

Portalloy 54

Dental alloy for ceramic-fused-to-metal technique

Composition

Au	Pd	Ru	Ag	Ga	In
54.2	31.0	0.1	4.8	0.9	9.0

in % by mass

Manufacturer

Wieland Dental + Technik GmbH & Co. KG
Schwenninger Straße 13 · D-75179 Pforzheim · Germany

Tests

We confirm that the following test for determining the biocompatibility of the dental alloy was carried out in accordance with the international standards ISO 10993 "Biological evaluation of medical devices" (ISO 10993-1, ISO 10993-5, ISO 10993-12) and ISO 7405 "Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials".

The test was performed according to the OECD directives "Good Laboratory Practice" (GLP) by the Institute BSL Bioservice Scientific Laboratories, Germany.

The test was coordinated and monitored by Dr. Henning + Co.

The test items were produced 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: "Test on extracts", XTT staining, ISO 10993-5, ISO 10993-12 and ISO 7405 (5.4.a)3)).

Test result:

Portalloy 54 had no cytotoxic potential

Dr. Henning + Co., Dental Engineering
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Basle, May 29, 2002