

Dr. G. Henning
Dental Engineering

Certificate

Biocompatibility Test

Material tested:

Wiron® light

PFM dental alloy, ISO 9693 (ISO 22674, Type 4)

**Composition/
in % by weight:**

Ni 64.5	Cr 22.0	Mo 10.0	Si 2.1	Nb, Mn, B < 1 %
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Manufacturer:

BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG

Technologiepark Universität · Wilhelm-Herbst-Str. 1 · 28359 Bremen, 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 10993-2, ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-12) and ISO 7405: 1997, "Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials". The tests were performed according to the OECD directive "Good Laboratory Practice" (GLP) by the Institute BSL Bioservice Scientific Laboratories. The tests were coordinated and monitored by Dr. Henning – Dental Engineering. The test specimens have been produced by a commercial dental laboratory according to the manufacturing instructions of BEGO.

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: 1999, ISO 10993-12: 2002 and ISO 7405: 1998, (5.4.a)3).

Test result:

Wiron® light had no cytotoxic potential.

Mutagenicity:

The mutagenicity was tested with the "Reverse Mutation Assay" using bacteria Salmonella typhimurium, ISO 10993-3: 2003, ISO 10993-12: 2002, EEC Directive 2000/32, L136 Annex 4D.

Test result:

Wiron® light was non-mutagenic.

Allergic sensitization:

The allergic sensitization was tested with the "Maximization-Test" (Magnusson-Kligman), ISO 10993-10: 2002, (6.3) "Tests for irritation and delayed-type hypersensitivity", ISO 10993-12: 2002, ISO 7405: 1997 (5.4.b)5), OECD 406-92 and Directive 92/69 EEC, B.6.

Test result:

Wiron® light did not cause allergic sensitization.

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Loerrach, 2007-02-15