Dr. Henning + Co.
Dental Engineering

Certificate

Biocompatibility Test

Material tested: **Wironit®**

Dental Casting Alloy, Typ 5, acc. to ISO 22674

Composition / in % by weight:

Co 64.0	Cr 28.65	Mo 5.0	Si, Mn, C

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: 1992, "Biological evaluation of medical devices" (ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-12), DIN EN 30993-1: 1994, and DIN EN ISO 7405: 1998 "Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials". The tests were performed according to the OECD code "Good Laboratory Practice" (GLP) by the Institutes RCC Ltd., Switzerland, and BSL Bioservice, Germany. The tests were coordinated and monitored by Dr. Henning + Co., Switzerland. The specimens were produced by lost wax casting procedure in a commercial dental laboratory, according to the instructions of the manufacturer BEGO Bremer Goldschlägerei GmbH & Co. KG.

Cytotoxicity:

The cytotoxic potential of the dental alloy was tested in vitro with L-929 fibroblasts: "Direct Cell Contact Assay", ISO 10993-5, DIN EN 30993-5, ISO 10993-12 and DIN EN ISO 7405: 1998 (5.4.a.3).

Test result: **Wironit® had no cytotoxic potential.**

Skin irritation and allergenic sensitization:

Skin irritation and allergenic sensitization were tested with the modified epicutaneous test according to Buehler, ISO 10993-10: 1995, (6.3), "Tests for irritation and sensitization", DIN EN ISO 7405: 1998 (5.4.b.5), OECD 406-92 and Directive 92/69 EEC B.6.

Test result: **Wironit® did not cause skin irritation or allergenic sensitization.**

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Dental Engineering
Steinenvorstadt 13
CH-4051 Basel

Basle, 13. 2. 98