

# Certificate

## Biocompatibility Test

**Material tested:**

**Wirobond® C**

Dental alloy for metal-to-ceramic restorations

**Composition/  
in % by mass:**

Co 61	Cr 26	Mo 6	W 5	Si 1	Fe 0.5	Ce 0.5	C max. 0.02
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**Manufacturer:**

**BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co.**

Technologiepark Universität · Wilhelm-Herbst-Str. 1 · D-28359 Bremen

**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/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 the OECD code "Good Laboratory Practice" (GLP) by the Institute RCC, Basle, Switzerland and Cytotest Cell Research, Rossdorf, Germany. The tests were coordinated and monitored by Dr. Henning + Co., Basle. The test specimens were produced by an independent commercial dental laboratory according to the instructions of the manufacturer BEGO by lost wax casting procedure.

### Cytotoxicity

The cytotoxic potential of the dental alloy was tested in vitro with L-929 fibroblasts: "Direct cell contact test" (ASTM F 813-83 (1988) and ISO 10993-5, EN 30993-5 and prEN ISO 7405:1995 (5.2.1.c)).

**Test result:**

**Wirobond® C had no cytotoxic potential.**

### Irritation and allergic sensitization

The skin irritation and 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 EEC Guidelines 93/21/EEC).

**Test result:**

**Wirobond® C did not cause any skin irritation or allergic sensitization.**

**Dr. Henning + Co.**

**Dental Engineering**

Steinenvorstadt 13, CH-4051 Basel

Basle, 06/26/95

