

# CERTIFICATE

## Biocompatibility Test

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Material tested

**ALLUX®**

Dental ceramic, EN ISO 6872

**Composition:**

Liner-, dentine- and enamel material:  
Silicate-glass ceramic, pigments

**Manufacturer**

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

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### Tests

We confirm that the following tests for determining the biocompatibility of the dental ceramic were carried out in accordance with the international standards ISO 10993, "Biological evaluation of medical devices" (ISO 10993-1, ISO 10993-2, 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 tests were performed according to the OECD directives "Good Laboratory Practice" (GLP) by the Institute BSL Bioservice Scientific Laboratories.

The tests were coordinated and monitored by Dr. Henning + Co.

The test items were produced by a commercial dental laboratory according to the instructions of Wieland Dental + Technik.

### Cytotoxicity

The cytotoxic potential of the dental ceramic 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

**ALLUX® had no cytotoxic potential.**

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**Dr. Henning + Co., Dental Engineering**  
Steinenvorstadt 13 · CH - 4051 Basel



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