

# CERTIFICATE

## Biocompatibility Test

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### Material tested

# Imagine<sup>®</sup> Reflex

Dental ceramic for ceramic-fused-to-metal technique

### Composition

**Opaque-, 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 EN ISO 10993, "Biological evaluation of medical devices" (EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-12), and EN 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 GmbH & Co. KG.

### Cytotoxicity

The cytotoxic potential of the dental ceramic was tested in vitro with L-929 fibroblasts.

Method: "Test on extracts", XTT staining, EN ISO 10993-5, EN ISO 10993-12, and EN ISO 7405 (5.4.a)3).

Test result:

**Imagine<sup>®</sup> Reflex had no cytotoxic potential**

**Dr. Henning + Co., Dental Engineering**

Steinenvorstadt 13 · CH - 4051 Basel



Basle, February 26, 2003