

CERTIFICATE

Biocompatibility Test

Material tested

ZENOTEC® Zr Bridge

white, colored and translucent

Dental Ceramic, EN ISO 6872

Composition

Zirconium-dioxide

$ZrO_2 + HfO_2, Y_2O_3, Al_2O_3$

94 5 <1

w/w %

Manufacturer

Wieland Dental + Technik GmbH & Co. KG
Schwenninger Straße 13 · 75179 Pforzheim, Germany

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" (EN ISO 10993-1, EN ISO 10993-2, 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 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, EN ISO 10993-5, EN ISO 10993-12 and EN ISO 7405 (5.4.a) 3).

Test result

ZENOTEC Zr Bridge had no cytotoxic potential

Dr. G. Henning, Dental Engineering
Unterer Lichsenweg 13 · D-79541 Lörrach

Lörrach, 2008-04-02