

C E R T I F I C A T E

Biocompatibility Test

Material tested:

Sakura Interaction

Dental ceramic , EN ISO 6872

Composition:

Paste opaque-, dentin- and incisal material: silicate glass-ceramic, pigments.

Manufacturer:

Elephant Dental B.V.
Verlengde Lageweg 10
1628 PM Hoorn
The Netherlands

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 10993-2, 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 by a commercial dental laboratory according to the instructions of Elephant Dental B.V.

Cytotoxicity:

The cytotoxic potential of the dental ceramic was tested in vitro with L-929 fibroblasts. Method: „Test on extracts“, XTT staining, EN ISO 10993-5:1999, EN ISO 10993-12:2002 and EN ISO 7405:1997 (5.4.a)3).

Test result:

Sakura Interaction had no cytotoxic potential.

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