Certificate

Biocompatibility Test

Material tested: **BioEthic®**
Universal dental alloy for the ceramic-fused-to-metal technique

Composition/ in % by weight: Au 86.70 Pt 10.75 Zn 1.50 In 0.20 Ag 0.03 Sn 0.10 Ir 0.02 Rh 0.40 Ta 0.30

Manufacturer:
Cendres & Métaux SA
Rue de Boujean 122
CH-2501 Biel-Bienne

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 10993-10, ISO 10993-12), DIN EN 30993-1:1994, and DIN EN ISO 7405: 1998 «Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials».
The tests were performed according to the OECD code «Good Laboratory Practice» (GLP) by the Institute BSL Bioservice, Germany.
The tests were coordinated and monitored by Dr. Henning + Co., Switzerland.
The specimens were produced by lost wax casting procedure by a commercial dental laboratory, according to the instructions of the manufacturer Cendres & Métaux SA

Cytotoxicity

The cytotoxic potential of the dental alloy was tested in vitro with L-929 fibroblasts:

«Test on extracts», XTT staining, ISO 10993-5, DIN EN 30993-5, ISO 10993-12 and DIN EN ISO 7405: 1998, (5.4.a.3).

Test result: **BioEthic® had no cytotoxic potential.**

Allergic sensitization

Allergic sensitization was tested with the Maximization Test according to Magnusson and Kligman.
ISO 10993-10: 1995, (6.3) «Tests for irritation and sensitization», DIN EN ISO 7405: 1998 (5.4.b.5)., OECD 406-92 and Directive 92/69/EEC B.6.

Test result: **BioEthic® did not cause allergic sensitization.**

Basle, 30/4/98

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