Certificate

Biocompatibility Test

Material tested: Esteticor Avenir®

Dental Alloy for ceramic-fused-to-metal technique

Composition/

in % by weight: Au 84.0 Pt 10.9 Pd 2.4 Zn 2.2 Ag 0.2 Fe 0.2 Ir 0.1 %

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 EN ISO 10993, «Biological evaluation of medical devices» (EN ISO 10993-1, EN ISO 10993-2, EN ISO 10993-5, EN ISO 10993-10, EN ISO 10993-12) and EN ISO 7405: 1997, «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.

Cytotoxicity

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

fibroblasts:

Method:

«Test on extracts», XTT staining, ISO 10993-5: 1999,

EN ISO 10993-12: 1996 and EN ISO 7405: 1998, (5.4.a)3).

Test result: Esteticor Avenir® had no cytotoxic potential.

Allergic sensitization

The allergic sensitization was tested with the Maxitmization Test (Magnusson-

Kligman), EN ISO 10993-10: 1995, (6.3) «Tests for irritation and

sensitization», EN ISO 7405: 1997 (5.4.b)5), OECD 406-92 and Directive

92/69/EEC, B.6.

Test result: Esteticor Avenir® did not cause allergic sensitization.

Basle, 6/11/2000 **Dr. Henning + Co.**

Dental Engineering Steinenvorstadt 13 CH-4051 Basel h. l. funny