

Certificate

Biocompatibility Test

Material tested:

Esteticor® N2

Dental alloy for metal-ceramic restorations, ISO 22674 and ISO 9693

Composition w/w%:

Au 15.2; Pt 0.2; Pd 52.0; Ag 20.0; In 6.0; Sn 5.4; Ga 1.0; Ru 0.2

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, Dental Engineering. The test items were produced by a commercial dental laboratory according to the manufacturing instructions of Cendres+Métaux.

Test result:

Cytotoxicity

The cytotoxic potential of the dental alloy was tested in vitro with L-929 fibroblasts. Method: «Test on extracts», XTT staining, EN ISO 10993-5: 1999, EN ISO 10993-12: 2007 and EN ISO 7405: 1997, (5.4.a)3).

Esteticor® N2 had no cytotoxic potential.

Test result:

Mutagenicity

The mutagenicity was tested with the «Reverse Mutation Assay» using bacteria Salmonella typhimurium, ISO 10993-3: 2003, ISO 10993-12: 2002, EEC Directive 2000/32, L136 Annex 4D.

Esteticor® N2 was non-mutagenic.

Test result:

Allergic sensitization

The allergic sensitization was tested in vivo: Method: Maximization Test (Magnusson-Kligman), EN ISO 10993-10: 2002, (6.3) «Tests for irritation and delayed-type hypersensitivity», EN ISO 10993-12: 2007, EN ISO 7405: 1997 (5.4.b)5), OECD 406-92 and Directive 92/69 EEC, B.6.

Esteticor® N2 did not cause allergic sensitization.

Loerrach, 2008-06-24

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