

CERTIFICATE

Biocompatibility Test

Material tested

dentaNEM

Dental alloy for ceramic-fused-to-metal technique, EN ISO 9693

Composition

Co	Cr	Mo	Fe	Nb	Si	Mn
63,3	28,6	5,9	<1%	<1%	<1%	<1%

w/w %

Manufacturer

Himalaya Dental
79, Rue du Professeur Pozzi
24100 Bergerac, France

Sales

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 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.

The test items were produced by a commercial dental laboratory according to the manufacturing instructions of the manufacturer.

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: 2002 and EN ISO 7405: 1997 (5.4.a) 3).

Test result

dentaNEM had no cytotoxic potential

Allergic sensitization

The allergic sensitization was tested in vivo.

Method: Maximisation Test (Magnusson-Kligman), EN ISO 10993-10: 2002, (6.3) "Tests for irritation and delayed-type hypersensitivity", EN ISO 10993-12: 2002, EN ISO 7405: 1997 (5.4.b) 5), OECD 406-92 and Directive 92/69 EEC, B.6.

Test result

dentaNEM did not cause allergic sensitization

Dr. Henning + Co., Dental Engineering

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Basle, September 10, 2004