

Certificate Bio Maingold® SG

CE 0197

High gold content dental casting alloy
(according to EN ISO 22674)

Chemical composition (Content in mass %)

Bio Maingold® SG	Au	Ag	Pt	Cu	Zn	Ir
	71,0	12,3	3,9	12,2	0,5	0,1

This Dental Alloy is free of Beryllium und Cadmium.

Manufacturer: Heraeus Kulzer GmbH

Biocompatibility: We certify that this product has been evaluated according to the internationally valid directives EN ISO 7405, "Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials" and EN ISO 10993-1, "Biological evaluation of medical devices". The evaluation covers, among other things, possible risk of cytotoxicity, allergisation, irritation, and genotoxicity. The studies conducted were carried out in independent testing facilities according to OECD directives and fulfil the requirements of GLP (Good Laboratory Practice).

The evaluation proves the biological compatibility of this dental alloy.

Corrosion: Corrosion testing was carried out at Heraeus Kulzer's testing facility according to the EN ISO 22674. The directive stipulates a total release of metal ions from the metallic dental material of not more than 200 µg/cm² over 7 days at 37°C.

Evaluation: Based on the above test and evaluation, this alloy is classified as biocompatible (biologically compatible) when used as intended. A clinical evaluation proved that specified characteristics and performance related requirements are fulfilled.

The conformity of Bio Maingold® SG with internationally valid directives is proven and certified by the Technical Control Board of Rheinland (CE 0197).

This certificate is subject to an internal approval process. It was created electronically and is valid without signature.