

## Testing of Biocompatibility

# Certificate PALA Mix&Match

**Material:**

Premium, Mondial, Idealis

**Composition:**

Cross-linked polymethylmethacrylate with inorganic fillers and colour pigments.

**Manufacturer:**

Heraeus Kulzer GmbH  
Schlätterstr. 2  
88142 Wasserburg, Germany

**Biological Evaluation/Testing:**

Hereby we confirm that the following tests or evaluations to declare biocompatibility according to internationally valid guidelines were performed: ISO 7405 Dentistry-preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials, pulp and dentine usage test. ISO 10993-1 Biological evaluation of medical devices, ISO 10993-3 Genotoxicity, ISO 10993-5 Cytotoxicity, ISO 10993-6 Implantation / local effects after implantation, ISO 10993-10 Irritation/Intracutaneous Reactivity, Sensitisation/LLNA, ISO 10993-11 Systemic Toxicity, Acute/Subacute/Subchronic Toxicity.

Tests on biocompatibility were performed by an external contract research institute according to the OECD quality standard "Good Laboratory Practice" (GLP). Test results were evaluated by an independent expert. PALA Mix&Match artificial teeth were classified as biocompatible according to ISO 10993 and ISO 7405.

**Declaration of conformity:**

The conformity was declared and accounted according to Directive 93/42/EEC and was certified by the notified body (TUEV Rheinland – CE 0197).

**Adverse Reactions:**

Appropriate tests showed no sensitizing potential for Premium, Mondial and Idealis.

**Contraindication:**

Until now none known.

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