

Testing of Biocompatibility

Certificate Pala Denture Acrylics

Material:

Cold curing resin: PalaXpress ultra, PalaXpress, Palapress, Palapress vario, Paladur

Heat curing resin: Paladon ultra, Paladon 65, Paladent 20

Composition:

Main components powder: Methylmethacrylate-Copolymer

Main components liquid: Methylmethacrylate, Dimethacrylate

Manufacturer:

Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau, 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 denture acrylics 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 Pala denture acrylics.

Contraindication:

The product contains polymerisable monomers (e.g. methylacrylates/acrylates), which may irritate the skin. The product should not come to use in the occurrence of irritative reactions or known allergies against resins on meth-/acrylatebasis.

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

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That's prosthetics.

CE 0197