

Material Information Pala Denture Acrylics

Material:

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

Heat curing resin: Paladon 65, Paladent 20

Composition:

Main components powder: Methylmethacrylate-Copolymer

Main components liquid: Methylmethacrylate, Dimethacrylate.

Biological Evaluation/Testing:

Hereby we confirm that tests or evaluations to declare biocompatibility were performed according to EN ISO 7405 and EN ISO 10993 series.

Declaration of conformity:

Our medical devices bear a CE marking according to the Council Directive 93/42/EEC.

We declare that these products meet all the provision of the aforementioned regulation.

Adverse Reactions:

Appropriate tests showed no sensitizing potential for Pala denture acrylics.

An allergic potential in predisposed persons cannot be excluded completely due to the presence of monomers such as methacrylates. For patients with a resin allergy history or when reactions are observed, the product is contraindicated. Monomers may also irritate the skin and the products should not be used in the occurrence of irritative reactions.

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

Safety data sheets and more information are available at our website www.kulzer.com

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Giving a hand to oral health.



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