

Material Information Pala Mix&Match

Material:

Pala Premium, Pala Mondial, Pala Idealis and the corresponding digital sets Pala Mondial 6/8 DS, Pala Idealis 8 DS and Pala Premium 6 DS, and PalaVeneer

Composition:

Cross-linked polymethylmethacrylate with inorganic fillers and colour pigments.

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 Premium, Pala Mondial, Pala Idealis and the corresponding digital sets Pala Mondial 6/8 DS, Pala Idealis 8 DS and Pala Premium 6 DS, and PalaVeneer.

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 kulzer.com

Contact in Germany

Kulzer GmbH
Leipziger Straße 2
63450 Hanau
Germany
info.lab@kulzer-dental.com
kulzer.com

Giving a hand to oral health.



KULZER
MITSUI CHEMICALS GROUP