

Material Information Artic Digital

Material:

Artic Digital

Composition:

Cross-linked polymethylmethacrylate with 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 Artic Digital.

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

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Giving a hand to oral health.



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