DEFINTIVE. FAST. SAFE.

VarseoSmile Crown plus

BIOLOGICAL SAFETY TESTS

Partners in Progress

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VarseoSmile Crown plus

About VarseoSmile Crown plus

VarseoSmile Crown plus is the world's first ceramic filled hybrid material designed for 3D printing permanent of dental restorations. Extensive tests have been performed to demonstrate the tolerability and biocompatibility of restorations made of VarseoSmile Crown plus.

Results

Despite the large total surface area of the test specimen, the tests performed did not result in any adverse reactions. From a chemical and biological perspective, VarseoSmile Crown plus is therefore suitable for definitive restorations, the scope of which could include up to a full set of teeth.

Test methods

The tests were performed in line with DIN EN ISO 10993 series of standards in accredited test laboratories. The total surface area of the test specimen for the relevant tests corresponded to the surface of 28 crowns in total, i.e. the equivalent of the restoration of a full set of teeth with VarseoSmile Crown plus.

Conclusion

Regardless of whether it's a single tooth or large-scale restoration with multiple crowned teeth: 3D-printed restorations made of VarseoSmile Crown plus display high biological safety and biocompatibility, regardless of the extent of restoration.

Test results

Test	Test subject	Results of the test laboratories and toxicological analyses
Chemical characteristics	Determination of leachable and extractable contents and substances	All organic and inorganic leachable substances are significantly below toxicologically relevant safety parameters.
Cytotoxicity	Determination of harmfulness to cells and tissues	Based on the results observed and under the chosen test conditions, no further cytotoxic potential is ascribed to the test object VarseoSmile Crown plus […].
Skin irritation	Determination of the potential to trigger skin irritation	Based on the results observed […], VarseoSmile Crown plus is not reactive under the conditions of this study […].
Skin sensitisation	Determination of the potential to trigger allergic skin reactions	Based on the results obtained in this study […], VarseoSmile Crown plus is classified as not sensitising under the conditions of this study […].
Pyrogenicity	Test of the potential to trigger inflammatory physical reactions, e.g. fever	Based on the results obtained in this study […], we can draw the conclusion that the test object VarseoSmile Crown plus […] is not pyrogenic.
Genotoxicity	Test of the potential to trigger changes in genetic material (DNA)	Based on the results obtained in this study […], we can draw the conclusion that the test object VarseoSmile Crown plus […] is not mutagenic.

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