

Material Information HeraCeram[®] Saphir

Veneering Ceramics (In accordance with EN ISO 9693 and EN ISO 6872)

Chemical Composition

Silicon Dioxide (SiO₂), Aluminium Oxide (Al₂O₃), Potassium Oxide (K₂O), Sodium Oxide (Na₂O), Lithium Oxide (Li₂O), Calcium Oxide (CaO), Boron Oxide (B₂O₃), Fluorine (F), Cerium(IV) Oxide (CeO₂), Tin(IV) Oxide (SnO₂), inorganic pigment.

Material Properties

| | CTE Indication α (25 – 500°C) [$\mu\text{m}/\text{mK}$] | Glass Transition Temperature (T _g) [°C] | Flexural Strength [MPa] | Hardness Vickers [HV5] |
|------------------|---|--|----------------------------|---------------------------|
| HeraCeram Saphir | 13.5 – 14.9 | 500 +/- 20 | 85 | 520 – 560 |

Bio-Compatibility

We confirm that the product was evaluated in accordance with the internationally valid standards EN ISO 7405: “Dentistry- Evaluation of biocompatibility of medical devices used in dentistry” and the series of EN ISO 10993: “Biological evaluation of medical devices”. The Assessment includes possible risks of cytotoxicity, sensitization, irritation and genotoxicity.

The testing was carried out in independent test institutions in accordance to the specifications of the OECD guidelines and met the GLP (Good Laboratory Practice) requirements. The evaluation confirms the biological tolerability of this material.

Chemical Solubility

The test of chemical solubility was conducted in accordance with the EN ISO 6872 standard “Dentistry – ceramic materials”. The standard specifies that the mass loss of the ceramic material over an exposure time of 16 h in 4 % acetic acid in a heating cabinet at 80 +/- 3°C must not exceed the limit of 100 $\mu\text{g}/\text{cm}^2$. The test showed that the solubility of the tested ceramic is < 30 $\mu\text{g}/\text{cm}^2$. HeraCeram Saphir shows a low chemical solubility and therefore the requirement of the ISO standard is fulfilled.

Assessment

On the basis of the above named tests and assessments, the ceramic HeraCeram Saphir is classified as biocompatible (biologically tolerable) when used as specified.

The dense and smooth surface structure is guaranteed antagonist and gingiva friendly. The ceramic is easy to polish and its high quality surface ensures a natural abrasion behavior and high resistance against plaque.

The Stabilised Leucite Structure (SLS) ensures that HeraCeram Saphir Ceramics are particularly resistant to stress. And the consistent level of microfine leucite crystals prevents chipping.

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

Contact in Germany

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Giving a hand to oral health.



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