ProBase® Hot Certificate of biocompatibility

Test material: ProBase® Hot denture base material

Manufacturer Ivoclar Vivadent AG, Bendererstrasse 2, FL-9494 Schaan, Liechtenstein

Classification ProBase Hot denture base material complies with ISO 20795-1:2013

standard and, given its chemical composition and polymerization temperature, belongs to the heat-curing polymers (Type 1, Class 1).

Water solubility Testing according to ISO 20795-1:2013

Limit for heat-curing polymers $\mu g/mm^3 < 1.6$ Example value for ProBase Hot $\mu g/mm^3 < 0.3$

Surface quality The surface quality is an important prerequisite for denture hygiene. The basal gloss in

ProBase Hot dentures suggests high resistance to microorganisms.

Test: Examining the colonization with Candida albicans (yeast)

Result: The ProBase Hot material shows low colonization with Candida

albicans.

Test institute: Poliklinik für Zahnärztliche Prothetik, Universitätsklinikum

Regensburg, Germany, Priv.-Doz. Dr. R. Lang

Cytotoxicity Cytotoxicity tests were conducted on cells of the mouse cell line L929

with extracts of ProBase Hot and comparable materials. The extracts did

not reveal any cytotoxic effects.

Genotoxicity The AMES reversion mutation test was conducted on bacterial cells

with extracts of ProBase Hot and comparable materials. The extracts

did not show any mutagenic effects.

Schaan, February 2025

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