ProBase® Cold Certificate of biocompatibility

Test material: ProBase® Cold denture base material

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

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

and, due to its chemical composition and polymerization temperature,

is classified as self-curing polymer (Type 2, Class 2).

Water solubility Testing according to ISO 20795-1:2013

Limit for self-curing polymers
Typical value ProBase Cold

 $\mu g/mm^3 \le 8$ $\mu g/mm^3 \le 1,5$

Cytotoxicity Cytotoxicity tests were performed using extracts of ProBase Cold and

comparable materials on L929 mouse fibroblast cell lines. The extracts

showed no cytotoxic effects.

Genotoxicity The AMES reversion mutation test was conducted on bacterial cells

using extracts of ProBase Cold and comparable materials. The extracts

exhibited no mutagenic effects.

Schaan, May 2025

Manufacturer.

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