

CERTIFICATE

of biocompatibility

VarseoSmile Crown^{plus}

VarseoSmile Crown^{plus} is a hybrid material for 3D printing of permanent restorations. This is a light-cured, ceramic filled, methacrylate-based resin for the production of permanent single crowns, inlays, onlays, and veneers. single crowns, inlays, onlays and veneers.

Manufacturer: **BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG**
Wilhelm-Herbst-Str. 1 · 28359 Bremen, Germany

Production: VarseoSmile Crown^{plus} is produced in accordance with ISO 9001 and ISO 13485. VarseoSmile Crown^{plus} is a class IIa medical device.

Mechanical properties: The mechanical requirements in accordance with ISO 4049 and ISO 10477 have been satisfied.

Tests and results: **Cytotoxicity**
A test for potential cytotoxicity in accordance with the internationally applicable ISO 10993-1: 2018; ISO 10993-5: 2009; ISO 10993-12: 2012; ISO 7405: 2018 standards has been performed. No cytotoxic potential was determined.

Final evaluation: It is hereby confirmed that the material has been evaluated in accordance with the internationally applicable EN ISO 10993: „Biological evaluation of medical devices“ and ISO 7405: „Dentistry – Evaluation of biocompatibility of medical devices used in dentistry“ standards.
The evaluation includes, amongst other things, possible risks such as cytotoxicity, sensitisation, irritation, and genotoxicity.
The tests conducted were performed in independent testing facilities in accordance with the specifications of the OECD guidelines and in compliance with the GLP (Good Laboratory Practice) requirements.
The evaluation confirms the biological compatibility when used in accordance with the intended purpose.

Date of issue: May 12th, 2020



Dr.-Ing. Stephan Kim
Chief Development and Innovation Officer

BEGO Bremer Goldschlägerei
Wilhelm Herbst GmbH & Co. KG



Dr. Roland Strietzel
Medical Devices Safety Officer

BEGO Bremer Goldschlägerei
Wilhelm Herbst GmbH & Co. KG