

# Certificate

## on the testing of biological compatibility

**Tested material:** Samples made of dental plastic produced using the 3D printing process from

- VarseoWax Surgical Guide
- VarseoWax Tray

**Manufacturer:** **BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG**

Wilhelm-Herbst-Str. 1 · 28359 Bremen, Germany

**Tests:** We hereby confirm that the following tests to determine biological compatibility have been performed:

- Release of monomers and accompanying substances as well as water solubility and water absorption as per DIN EN ISO 20795-2:2010-08  
“Dentistry – Base polymers – Part 2: Orthodontic base polymers”
- Identification of other substances which are released from the samples by means of mass spectrometry based on a self-validated procedure
- Disinfectant stability (example isopropyl) based on a self-validated procedure
- DNA change from the addition of monomers based on a self-validated procedure

The tests were performed using modified accredited testing methods as per DIN EN ISO 17025 by the Central Institute of Medical Services of the German Federal Armed Forces Munich, Munster office. The tests were coordinated and monitored by Prof. Dr. Constantin von See/Danube Private University, Krems an der Donau/Austria. The samples were produced at BEGO both manually and using the 3D printing process by way of comparison.

**Test results:**

- The requirements of the above standard in terms of water solubility and absorption were satisfied. The amount of monomers and accompanying substances released was far below the limit values.
- No further substances were released from the samples produced using 3D printing which were different to the samples produced manually.
- The samples demonstrated chemical and physical resistance to isopropyl.
- No DNA addition products were identified.

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