

Certificate of Biocompatibility

Chamber of Commerce
Utrecht 30063196
VAT 809415094B01

We,

Vertex-Dental B.V.
Centurionbaan 190
3769 AV Soesterberg,
The Netherlands

Hereby declare under our sole responsibility that the CE marked product to which this declaration relates,

Formlabs Dental SG
3D printing material

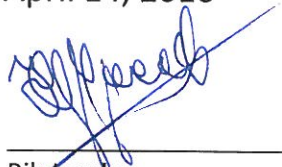
has been tested on biocompatibility according to the ISO 10993-1:2009 at NAMSA, Chasse sur Rhône in France. Devices printed with Dental SG on a Formlabs printer and post-cured according to the instructions for use, meet the applicable requirements of ISO 10993-1 and USP Class VI, and are biologically safe.

The product were tested on:

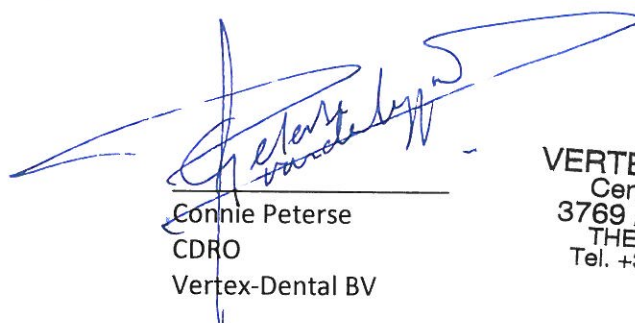
- Cytotoxicity test	Testreport 177178
- Sensitization	Testreport 168884
- Irritation	Testreport 168883
- Systemic toxicity (acute toxicity)	Testreport 168888
- Genotoxocity	Testreport 170296

The results in these tests show that the product meets the requirements of ISO 10993-1:2009 Biological Evaluation of Medical Devices.

Zeist, April 14, 2016



Rik Jacobs
CEO
Vertex-Dental BV



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CDRO
Vertex-Dental BV

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