EC Declaration of Conformity

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 liquid for surgical guide

Product codes are available in the annex.

has been classified as Class I, according to Annex IX, rule 5, and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC.


This declaration is made on base of the quality assurance certificate ISO 13485:2012 No BE12/2235729 Issue 3, valid until 17-12-2018 delivered by:
SGS United Kingdom Ltd. Systems & Services Certification
Rossmore Business Park
Ellesmere Port
Cheshire CH65 3EN
United Kingdom

This Declaration of conformity covers batches produced as of batches:
XN141N01

Soesterberg, April 18th, 2016

Mrs. N.C. Peterse – van der Koppel
Chief Development & Regulatory Officer
**Annex I: Product references Formlabs Dental SG**

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