Vertex Dental

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Chamber of Commerce
Utrecht 30063196
VAT 809415094B01

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.

and is conformity with EN ISO 1641:2009; EN ISO 10993-1:2009/AC2010; EN ISO 10993-3:2014; EN ISO 10993-5:2009; EN ISO 10993-11:2009 and EN ISO 14971:2012.

and is subject to the procedure set out in Annex VII of the Council Directive 93/42/EEC 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

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Chief Development & Regulatory Officer

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Annex I: Product references Formlabs Dental SG

Description	size	article number
Formlabs Dental SG	1000 l	RS-F2-DGOR-01

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