

EC Declaration of Conformity

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,

NextDent™ Ortho Clear

Productcodes are available in the annex.

has been classified as Class IIa, 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 10993-3:2009, EN ISO 10993-5:2009, EN ISO 10993-11 and EN 908:2008.

and is subject to the procedure set out in Annex II (excluding section 4) of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

This declaration is made on base of the EC Certificate Full Quality Assurance System N° BE12/223574916 Issue 6, valid until 17-12-2017 delivered by:

Notified Body n° 0120
SGS United Kingdom Ltd.
202B Worle Parkway
Weston-super-Mare, BS22 6WA
United Kingdom

This Declaration of conformity covers batches produced as of batches: XN175N01.

Soesterberg, April 29 2016


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Mrs. N.C. Peterse – van der Koppel
Chief Development & Regulatory Officer

Annex I: Product references NextDent™ Ortho Clear

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Description	Size	Productcode
NextDent Ortho Clear / Clear	1000 g	NDOCCL01000