

## 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,

**Nextdent™ SG**  
*Surgical guide*

Productcodes 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.

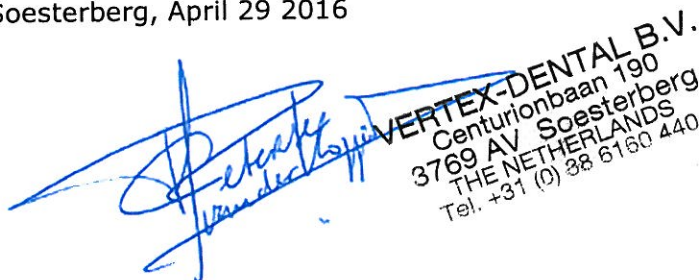
and is conformity with EN ISO 1641:2009; EN ISO 10993-1:2009/AC2010; EN ISO 10993-3:2014; EN ISO 10993-5:2009; EN ISO 10993-11:2009, EN ISO 14971:2012 and EN 908:2008.

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 N° BE12/223574929 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:  
XN175N01

Soesterberg, April 29 2016



**VERTEX-DENTAL B.V.**  
Centurionbaan 190  
3769 AV Soesterberg  
THE NETHERLANDS  
Tel. +31 (0) 88 6160 440

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

## Annex I: Product references Nextdent™ SG

Description	size	articlenumber
Nextdent SG Orange	1000 g	NDSGOR01000