

## 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™ Base

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 10993-3:2014; 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 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 17-12-2018 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: XN103N01.

Soesterberg, March 9 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™ Base

Description	Size	Productcode
NextDent Base / Pink	1000 g	NDBAPI01000