

## EC Declaration of Conformity

Chamber of Commerce  
Utrecht 30063196  
VAT 809415094B01

We,  
Vertex-Dental B.V.  
Johan van Oldenbarneveltlaan 62  
3705 HJ Zeist,  
The Netherlands

Hereby declare under our sole responsibility that the CE marked product to which this declaration relates,

### NextDent™ Ortho Rigid

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 10993-3:2009; EN ISO 10993-5:2009.

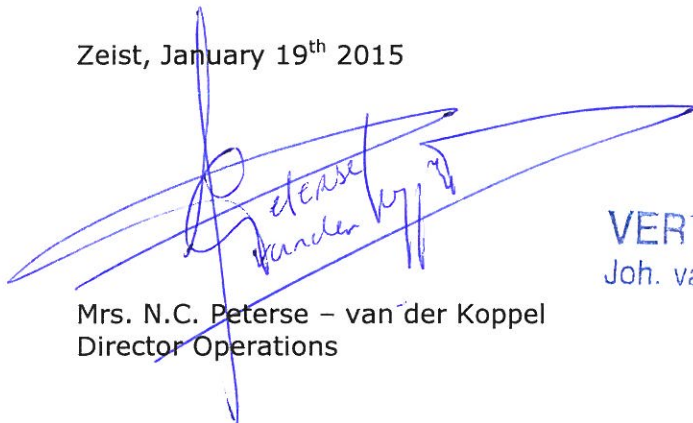
and is subject to the procedure set out in Annex VII of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

This declaration is made on base of the quality assurance certificate N° BE12/223574916, 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: XR041N01.

Zeist, January 19<sup>th</sup> 2015



Mrs. N.C. Peterse – van der Koppel  
Director Operations

VERTEX-DENTAL B V  
Joh. van Oldenbarneveltlaan 62  
3705 HJ Zeist  
Nederland

## Annex I: Product references Nextdent™ Ortho Rigid

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Description	Size	Productcode
NextDent Ortho Rigid	1000	NDORVV001000CCLEAR