

Declaration of Conformity

Hereby Vertex-Dental B.V. declares that the product:

Nextdent™ C&B
Temporary crown & bridge

conforms to the EC Directive 93/42/EEC Medical Devices, Annex VII.

Nextdent™ C&B is classified as Class I Medical Device.
This Declaration of Conformity covers all medical devices Nextdent™ C&B produced as of XT111N01. A complete list with the product references is available in the attached annex.

The product as stated in this declaration fulfils the requirements of the ISO standards ISO 10477:2004 and ISO 7405:2009. A complete list of the applied standards is available in the technical file of this product.

Vertex-Dental BV produces and distributes Vertex™ and Nextdent™ products according a quality system based on EN-ISO 13485:2003 and EN-ISO 9001:2008. The corresponding certificates are valid until December 2015 and are submitted SGS United Kingdom Ltd.. We refer to our technical product files, which are part of our quality assurance system. The competent authority is permitted to inspect these files.

Notified Body: 0120
SGS United Kingdom Ltd.
Inward Way
Rossmore Business Park
Ellesmere Port, CH65 3EN
United Kingdom

Zeist, March 10th 2014

Mr. H.G. Jacobs
Director Marketing & Sales

Vertex-Dental B.V.
Johan van Oldenbarneveltlaan 62
3705 HJ Zeist


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

Annex I: Product references Nextdent™ C&B

| Description | size | articlenumber |
|----------------|---------|-----------------|
| Nextdent CB A2 | 1000 ml | NDCBVV001000CA2 |
| Nextdent CB A3 | 1000 ml | NDCBVV001000CA3 |