

## Declaration of Conformity

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

### Nextdent™ Tray

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

Nextdent™ Tray is classified as Class I Medical Device.

This Declaration of Conformity covers all medical devices Nextdent™ Tray 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 standard 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.  
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Zeist, March 10<sup>th</sup> 2014

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## Annex I: Product references Nextdent™ Tray

Description	size	articlenumber
Nextdent Tray Pink	1000 ml	NDTRVV001000CPINK
Nextdent Tray Blue	1000 ml	NDTRVV001000CBUE