EC Certificate Full Quality Assurance System: Certificate BE12/223574916



The management system of

## Vertex-Dental B.V.

Centurionbaan 190 3769 AV Soesterberg, The Netherlands

has been assessed and certified as meeting the requirements of

### Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 02 September 2017 until 17 December 2020 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 21 November 2018 Issue 10. Certified since 18 December 2012

Certification is based on reports numbered BE/AND 2/1243.QMD

Authorised by

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EC Certificate Full Quality Assurance System: Certificate BE12/223574916, continued

### Vertex-Dental B.V.

### Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 10

Detailed scope

#### Non-sterile dental devices:

Denture base resins, heat-cured:

Vertex™ Rapid Simplified

Vertex™ Implacryl

Vertex™ Regular

DB-20

Hot Curing 20 minutes type C Hot Cure material type C Hot Curing 20 minutes type D Hot Cure material type D Vertex™ BasiQ20 High Impact D Platinum Hi

Precidon J-Cryl+

Holland Dental Rapid Simplified Holland Dental Implacryl

#### Denture base resins, self-cured

Vertex™ Castapress
Vertex™ Castaquick
Vertex™ Castavaria
Vertex™ Self Curing
Vertex™ Self Curing Quickset
Vertex™ Implacryl Cold
Pour material B
Pour material D
Repair material B
Repair material C

Repair material D Pour D CV

Holland Dental Castapress
Holland Dental Self Curing Slow Set
Holland Dental Self Curing Regular Set
Precidur Self
Precipress
Jet Denture Repair



EC Certificate Full Quality Assurance System: Certificate BE12/223574916, continued

# Vertex-Dental B.V.

### **Directive 93/42/EEC**

on medical devices, Annex II (excluding Section 4)

Issue 10

Dental relines, soft Vetex™ Soft

Holland Dental Soft

Orthodontic resins, self-cured

Vertex™ Orthoplast

Vertex™ Orthoplast LP Vertex™ Orthoplast Repair

Ortho D

Holland Dental Orthoplast

Resins for individual colour characterisation

Vertex<sup>™</sup> Acryl Stain

Orthodontic resins, Photo-Cured:

NextDent™ Ortho rigid

Novux 3D Splint

NextDent™ Ortho clear

E-Guard

Dental LT Clear

**Denture Base resins, Photo-Cured** 

NextDent™ base

NOvux 3D Base

E-Denture

**SR100-BS** 

Crown and bridge resins, Photo cured

NextDent™ C&B Novux 3D Temp

E-Dent 400

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market