

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 22 December 2018 until 17 December 2020  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 21 November 2018  
Issue 12. Certified since 18 December 2012

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

Authorised by

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## Vertex-Dental B.V.

### Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 12

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





## Vertex-Dental B.V.

### Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 12

**Orthodontic resins, self-cured**

Vertex™ Orthoplast  
Vertex™ Orthoplast LP  
Vertex™ Orthoplast Repair  
Ortho D  
Holland Dental Orthoplast

**Orthodontic resins, Photo-Cured:**

NextDent™ Ortho rigid  
Novux 3D Splint  
NextDent™ Ortho clear  
E-Guard  
Dental LT Clear  
Ceramill Ortho Rigid

**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  
NextDent C&B MFH  
Ceramill C&B MFH

**Cobalt-chromium alloy for removable crown and bridges**

Laserform CoCr (c)

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

