

EC Certificate Full Quality Assurance System: Certificate BE19/819943693

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 pages 2 and 3 of this certificate.**

This certificate is valid from 06 May 2021 until 24 May 2024  
and remains valid subject to satisfactory surveillance audits.  
Issue 7. Certified since 18 December 2012

Certification is based on reports numbered BE/AND 12/1243.QMD

Authorised by

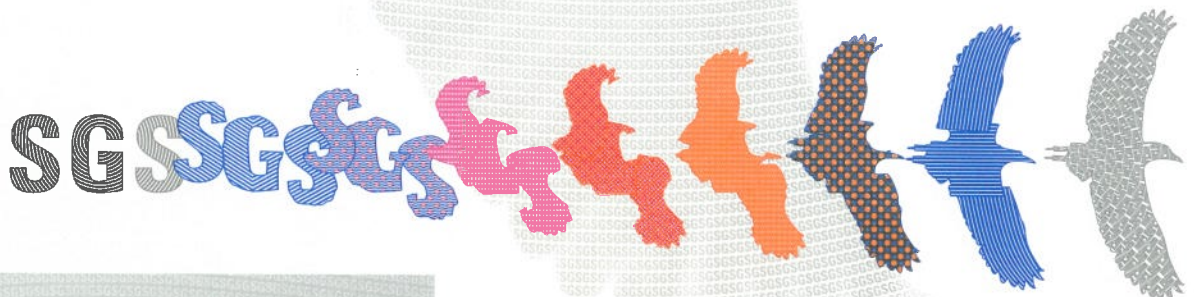
Global Medical Devices Head of Notified Body

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## Vertex-Dental B.V.

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

Issue 7

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
- 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
- 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

##### Orthodontic resins, self-cured

- Vertex™ Orthoplast
- Vertex™ Orthoplast LP
- Holland Dental Orthoplast

# Vertex-Dental B.V.

## Directive 93/42/EEC

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### Orthodontic resins, self-cured

Vertex™ Orthoplast  
Vertex™ Orthoplast LP  
Holland Dental Orthoplast

### Orthodontic resins, Photo-Cured:

NextDent™ Ortho rigid  
NextDent™ Ortho clear  
E-Guard  
Dental LT Clear  
Ceramil Ortho Rigid  
NextDent Ortho Flex  
Ceramill Ortho Flex

### Crown and bridge resins, Photo cured

NextDent™ C&B  
E-Dent 400  
NextDent C&B MFH  
Ceramil C&B MFH

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

Laserform CoCr ©

### Denture Base resins, Photo-Cured:

NextDent™ base  
NextDent Denture 3D+  
Ceramill Denture 3D+

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.