

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 8 August 2016 until 17 December 2020 and  
remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 21 November 2018.  
Issue 8. Certified since 18 December 2012.

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

Authorised by

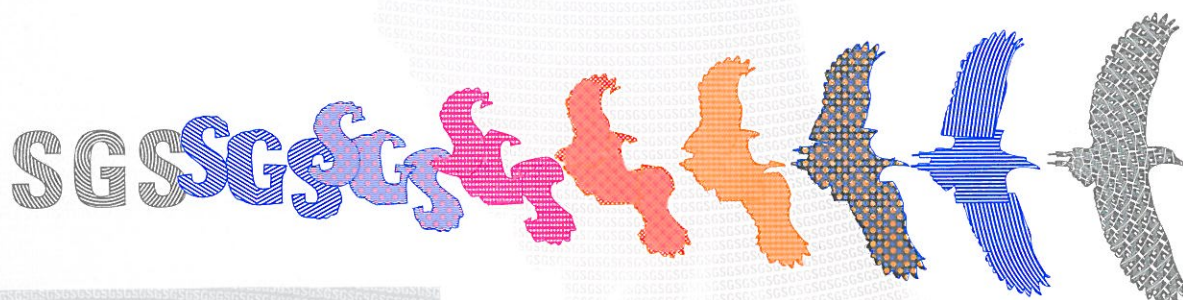


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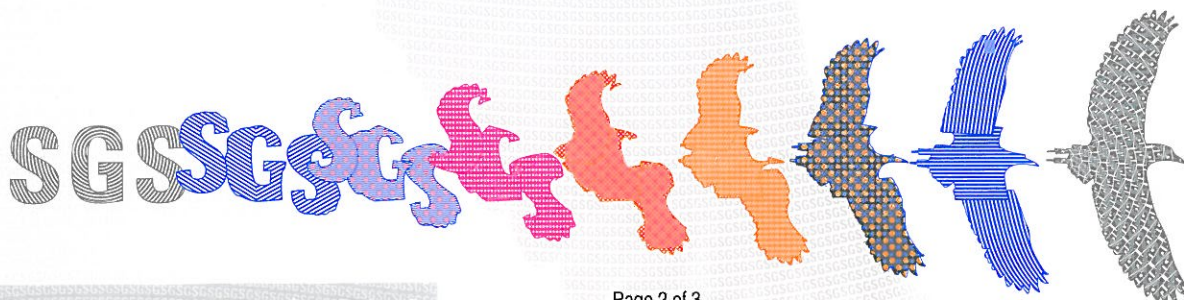
Detailed scope

### 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  
J-Cryl+ Rapid Repair





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### Dental relines, soft:

Vertex™ 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 characterization:

Vertex™ Acrylic Stain

### Orthodontic resins, Photo-Cured:

NextDent™ Ortho Rigid  
Novux 3D Splint

### Denture Base resins, Photo-Cured:

NextDent™ Base  
Novux 3D Base  
E-Denture

### Crown and bridge resins, Photo-Cured:

NextDent™ C&B  
Novux 3D Temp  
E-Dent 400

