

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 13 April 2017 until 17 December 2020
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 21 November 2018

Issue 9. Certified since 18 December 2012

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

Authorised by

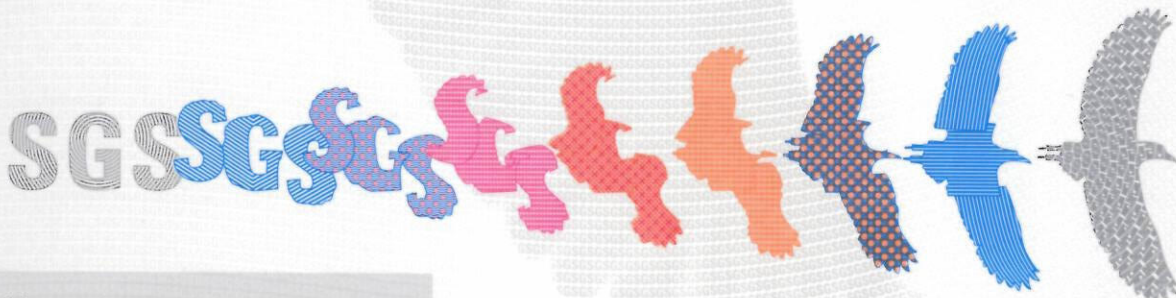


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continued

Vertex-Dental B.V.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 9

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

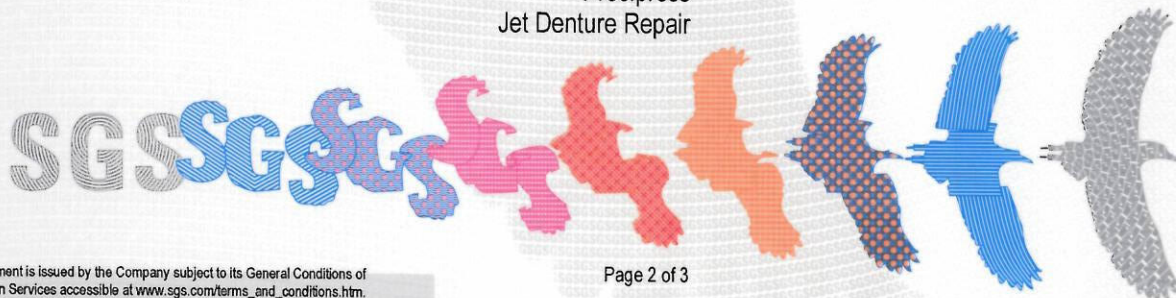
Holland Dental Self Curing Slow Set

Holland Dental Self Curing Regular Set

Precidur Self

Precipress

Jet Denture Repair



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continued

Vertex-Dental B.V.

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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™ Acryl Stain

Orthodontic resins, Photo-Cured:

NextDent™ Ortho rigid

Novux 3D Splint

NextDent™ Ortho clear

E-Guard

Denture Base resins, Photo-Cured

NextDent™ base

NOvux 3D Base

E-Denture

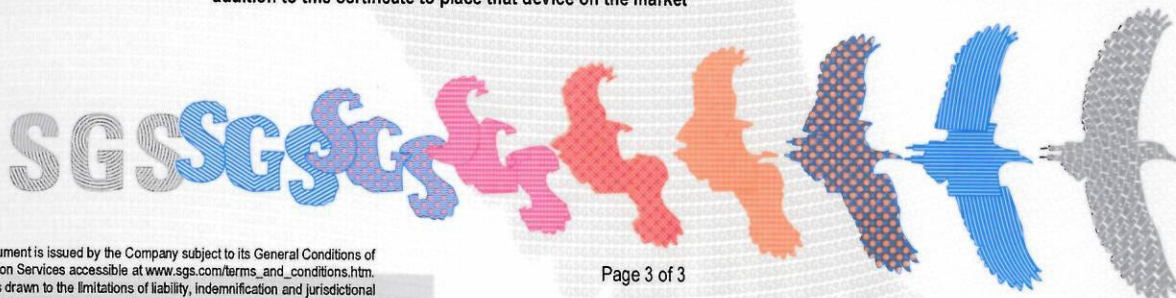
Crown and bridge resins, Photo cured

NextDent™ C&B

Novux 3D Temp

E-Dent 400

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



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