

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 and 3 of this certificate.

This certificate is valid from 22 July 2019 until 17 December 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 21 November 2021
Issue 15. Certified since 18 December 2012

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

Authorised by

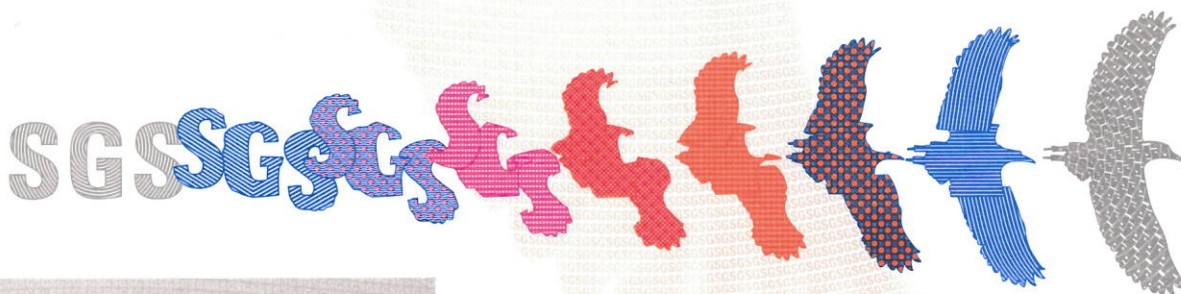
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Page 1 of 3



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 15

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

Precidion

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

Page 2 of 3



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 15

Detailed scope

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

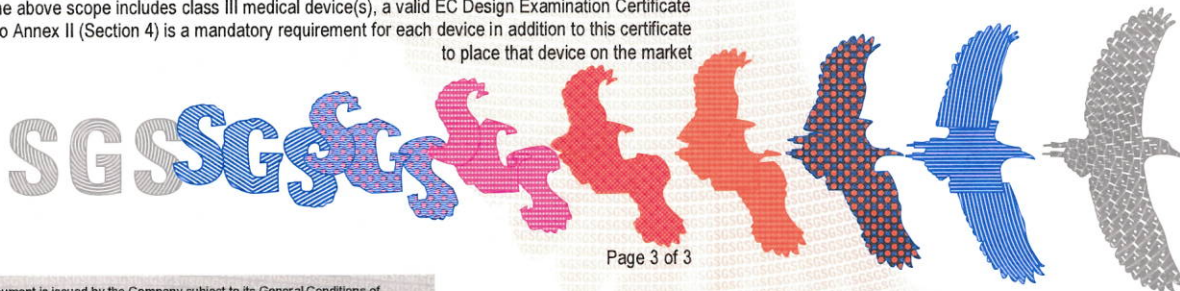
Crown and bridge resins, Photo cured

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



Page 3 of 3

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