



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 20 August 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 18 December 2012
and first certified by SGS Belgium NV since 08 October 2019

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

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LFMD5007 - Certificate CE1639 Annex II-4, EN rev. 02

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Certificate BE19/819943693 continued

Vertex-Dental B.V.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

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

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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

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
E-Denture
NextDent Denture 3D+
Ceramil 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.

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