SGS

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

ander

SGS Belgium NV, Notified Body 1639

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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 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 Certificate BE19/819943693 continued



Vertex-Dental B.V.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 7

Detailed scope

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