

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



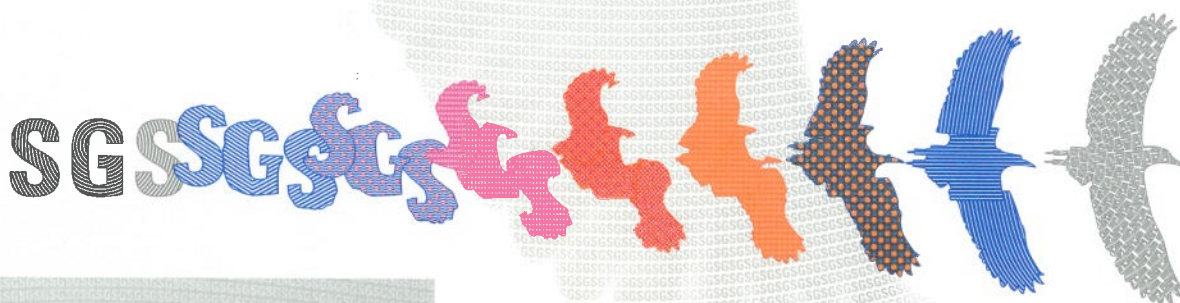
Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 3



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

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.