

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 8 August 2016 until 17 December 2020 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 21 November 2018.
Issue 8. Certified since 18 December 2012.

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

Authorised by

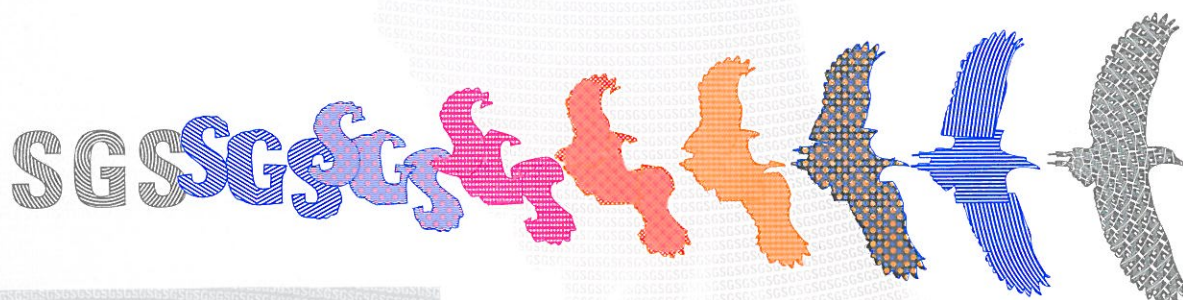


SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M3

Page 1 of 3



Vertex-Dental B.V.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

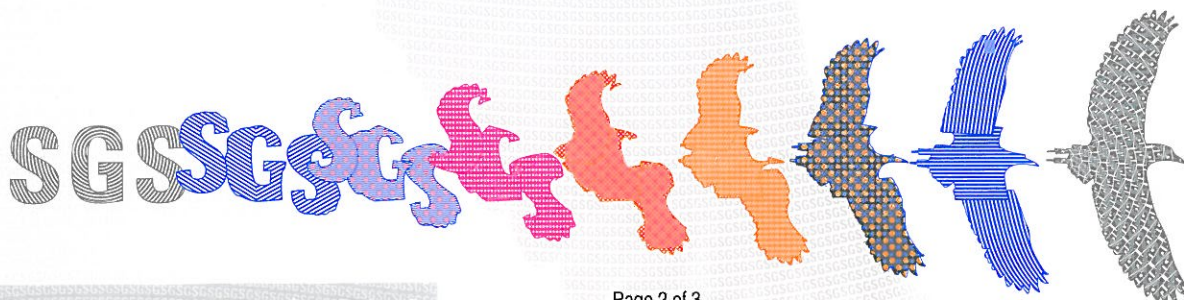
Detailed scope

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
J-Cryl+ Rapid Repair



Vertex-Dental B.V.

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope

Dental relines, soft:

Vertex™ 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 characterization:

Vertex™ Acrylic Stain

Orthodontic resins, Photo-Cured:

NextDent™ Ortho Rigid
Novux 3D Splint

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

