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 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



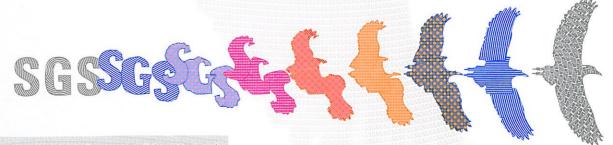
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EC Certificate Full Quality Assurance System: Certificate BE12/223574916, continued

Vertex-Dental B.V. Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope

Denture base resins, heat-cured:

Vertex™ Rapid Simplified Vertex[™] Implacryl Vertex™ Regular

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





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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 8

Detailed scope

Dental relines, soft:

Vertex[™] Soft Holland Dental Soft

Orthodontic resins, self-cured:

Vertex[™] Orthoplast LP Vertex[™] Orthoplast Repair 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





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