

APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60020154 0001

Report No.: 21132895 002

Manufacturer: Vertex-Dental B.V.
Johan van Oldenbarneveltlaan 62
3705 HJ Zeist
Netherlands



Scope: Design/Development and Production of Dental Devices
Products: see Attachment

Date of Expiry: 17.12.2012

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 18.12.2007

Notified Body



Dipl.-Ing. I. Munkler

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

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Scope: Products:

- Denture Base Resins, Heat-Cured
- Denture Base Resins, Self-Cured
- Denture Relines, Soft
- Orthodontic Resins, Self-Cured
- Resins for individual colour characterisation
- Temporary crown and bridge material, Self-Cured

Cologne, 18.12.2007



Dipl.-Ing. I. Munkler