

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

Registration No.: HD 2110688 01

Report No.: C 2171045 E 01

Manufacturer: Jeneric/Pentron, Inc.
53 North Plains Industrial Rd.
Wallingford, CT 06492
USA

Scope: Design, Development, Production and Distribution
of Dental Materials

Products: see attachment

Replaces Approval, Registration No. HD 9610679

Date of Expiry: 13.05.2006

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, 14.05.2001



Notified Body

Dr. Viola
Dr. Viola

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 Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

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



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

Attachment to
Registration No.: HD 2110688 01
Report No.: C 2171045 E 01

Manufacturer: Jeneric/Pentron, Inc.
53 North Plains Industrial Rd.
Wallingford, CT 06492
USA

Scope: Products:

Composites
Non Precious Alloys
Precious Alloys
Bonding Agents
Dental Porcelain

Cologne, 14.05.2001



Dr. Viola