

APPROVAL

EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60018258 0001

Report No.: 21130563 002

Manufacturer: DiaDent Group International
#19-9, Songjung-dong,
Heungduk-gu, Cheongju,
361-290 Choongchong Buk-do
South Korea

Scope: Manufacturing of Dental Medical Devices
Products: see attachment

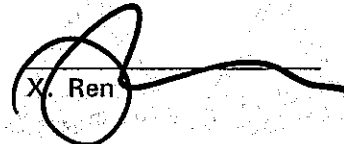
Date of Expiry: 22.05.2012

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.



Notified Body

Cologne, 21.08.2008

X. Ren 

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

Attachment to
Registration No.: **DD 60018258 0001**
Report No.: **21130563 003**

Manufacturer: **DiaDent Group International**
#19-9, Songjung-dong,
Heungduk-gu, Cheongju,
361-290 Choongchong Buk-do
South Korea

Scope: Product: Apex Locators

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

Product: Paper Points

For the following medical devices the scope covers only the aspects of manufacture concerned with conformity of products with the metrological requirements:

Product: Endo Stops

Cologne, 21.08.2008



Certification Body

X. Ren