TÜVRheinland®

APPROVAL

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

Registration No.: HD 60027766 0001

Report No.: 21143465 002

Manufacturer:
medentis medical GmbH
Gartenstr. 12
53507 Dernau
Deutschland

Scope:
Design/development and manufacture of products related to dental implantology

(see attachment for products and sites included)

Replaces Approval, Registration No.: HD 60014662 0001

Date of Expiry: 17.12.2014

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.

Notified Body

TÜV Rheinland Product Safety GmbH – Zertifizierungsstelle

Cologne, 2009/12/18

Dipl.-Ing. U. Frenkert

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