



APPROVAL

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

Registration No.: DD 60015310 0001

Report No.: 28202159 002

Manufacturer: TensioMed Tudományos
Informatikai és
Orvos-Elektronikai Kft.
Köér u. 2/d
1103 Budapest
Hungary

Scope: Manufacturing and sales of blood pressure measuring
devices and non-invasive haemodynamical diagnostic devices

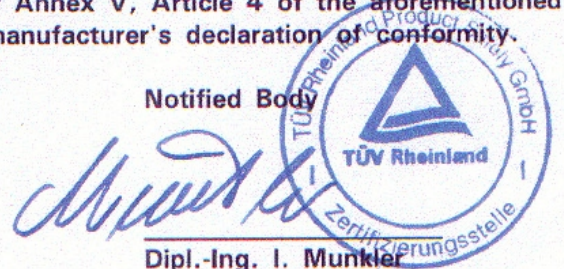
Replaces Approval, Registration No.: DD 60004957 0001

Date of Expiry: 12.07.2011

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.

Cologne, 13.07.2006

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