

# EC – CERTIFICATE

## Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 06 06 14553 028



Product Service

**Manufacturer:**

**Ernst Biegler GmbH  
Medizinelektronik**

Allhangstrasse 18 a  
3001 Mauerbach  
AUSTRIA

**Facility(ies):**

Ernst Biegler GmbH Medizinelektronik  
Allhangstrasse 18 a, 3001 Mauerbach, AUSTRIA

**Product Category(ies):**

**Ventilators and respiratory training apparatus, blood infusion warmers, cooling systems for medical solutions, electrical stimulation therapy devices, pressure infusion devices, magnetic field therapy, extension sets for blood- and infusionwarmer, heating bag systems and biopsy needles**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.:

70121423

Valid until:

2010-04-03



Date: 2006-07-11

TÜV SÜD PRODUCT SERVICE GMBH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.