

CERTIFICATE

No. Q1N 04 06 14553 025



Holder of Certificate:



Allhangstr. 18 a, A – 3001 Mauerbach

Facility(ies):

**Ernst Biegler Ges. mbH
Medizinelektronik**

Allhangstr. 18 a
3001 Mauerbach
Österreich

Certification Mark:



Scope of Certificate:

Design and development, production and distribution of ventilators and respiratory training apparatus, blood and infusion warmers, pressure infusion devices, fibrin sealant application systems, cooling systems for medical solutions, olfactometers, electrical stimulation therapy devices, laboratory and diagnosis equipment

Applied Standard(s):

EN ISO 13485:2003
Medical Devices – Quality Management Systems -
Requirements for regulatory purposes

The Certification Body of TÜV PRODUCT SERVICE GMBH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standards. See also notes overleaf.

Report No.:

70067658

Valid until:

2007-06-30

Date: 2004-06-14



TÜV PRODUCT SERVICE GMBH
Zertifizierstelle
Ridlerstraße 65 D-80339 München
Gruppe TÜV Süddeutschland

Akkreditiert durch



Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten

vertreten im



ZLG-ZQ-999.98.12-46