

Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

**Proven Process
Medical Devices, Inc.
110 Forbes Boulevard
Mansfield MA 02048
USA**

has established and applies a quality management system for medical devices
for the following scope:

**Contract services for the design and development, production
and servicing of medical devices, active implantable
medical devices and in vitro diagnostic medical devices
Product groups: see attachment**

Proof has been furnished that the requirements specified in

EN ISO 13485:2003 + AC:2007

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60021064 0001

An audit was performed. Report No.: 30793319 001

This Certificate is valid until: 06.03.2013



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Cologne, 17.07.2008



Certification Body


Dr. H. Lüdemann

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TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: SX 60021064 0001
Report No.: 30793319 001

Organization: Proven Process
Medical Devices, Inc.
110 Forbes Boulevard
Mansfield MA 02048
USA

Scope: Medical device and active implantable medical device product groups:
Vascular catheters, intraspinal catheters, needles, syringes, vascular introducers, guide wires, intravenous infusion sets, vascular access devices, drainage systems pacemakers, neurostimulators, pulse generators defibrillators, cardiac assist devices, ECG monitors EEG monitors, ICP monitors, blood pressure monitors patient monitors, infusion pumps, active implantable infusion pump systems, elastomeric pumps, transdermal drug delivery systems disposable surgical instruments, endoscopes, endoscope reprocessors, surgical instrument reprocessors, electrosurgical instruments and generators, catheter control systems, diagnostic ultrasound systems, therapeutic ultrasound devices, imaging and monitoring workstations computer aided detection (CAD) system, medical device software



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Product Safety GmbH
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Doc 2/2, Rev. 0

Attachment to
Registration No.: SX 60021064 0001
Report No.: 30793319 001

Organization: Proven Process
Medical Devices, Inc.
110 Forbes Boulevard
Mansfield MA 02048
USA

Scope: In vitro diagnostic medical device product groups:
Glucose monitoring systems, in vitro diagnostic
analyzers and software used in the management,
detection or diagnosis of cancer, disease status,
immune status, autoimmune status or endocrine disorders



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