

Certificate

The Certification Body of
TÜV Rheinland LGA Products 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, in vitro diagnostic medical devices
(see attachment for additional sites and product groups)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**


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

Effective Date: 2017-09-27
Certificate Registration No.: SX 60122539 0001
An audit was performed. Report No.: 31790697 001
This Certificate is valid until: 2019-03-30

Certification Body



Date 2017-09-21


M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60122539 0001
Report No.: 31790697 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
- Pulmonary Devices
- Pacemakers
- Neurostimulators
- Pulse Generators
- Defibrillators

Certification Body



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Organization: Proven Process
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Scope:

- Cardiac Assist Devices
- ECG Monitors
- EEG Monitors
- ICP Monitors
- Blood Pressure Monitors
- Patient Monitors
- Infusion Pumps
- Active Implantable Infusion Pumps and Accessory Kits
- Elastomeric Pumps
- Transdermal Drug Delivery Systems
- Disposable Surgical Instruments
- Endoscopes
- Endoscope Reprocessors

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Scope:

- Surgical Instrument Reprocessors
- Electrosurgical Instruments and Generators
- Catheter Control Systems (remote catheter manipulator)
- Diagnostic Ultrasound Systems
- Therapeutic Ultrasound Devices
- Imaging and Monitoring Workstations
- Computer Aided Detection (CAD) System
- Medical Device Software
- Angiographic Injectors
- Angiographic Syringes

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Organization: Proven Process
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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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