

# 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**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**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**



**Date:** 2017-09-21

  
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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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**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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**M.Sc. M. Aihara**