

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 product groups included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date: 2019-04-01
Certificate Registration No.: SX 60136226 0001
An audit was performed. Report No.: 31790697 002
This Certificate is valid until: 2020-09-26

Certification Body



Date 2019-04-01



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 60136226 0001
Report No.: 31790697 002

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: 2019-04-01



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LGA Products GmbH
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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

Certification Body



Date: 2019-04-01



Songir

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Organization: Proven Process
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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

Certification Body



Date: 2019-04-01



S. Liu

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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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

Certification Body



Date: 2019-04-01

